

1. One cannot maintain a continuous exponentially decaying flow of medication which is required for the treatment of some disorders;

2. The absence of a continuous, controllably decaying outward flow from the pump outlet (such as a catheter) can result, due to the body's functioning, in the clogging of the outlet (or catheter) tip; and

3. The absence of flow resistance or restriction at the output allows the possibility of an inadvertently high medication flow rate into the body in the event of bellows pump runaway."

Page 4, ~~line 17~~, delete "entering" and replace therefore --being inadvertently released into--. This amendment was previously incorrectly requested for line 7.

In the Description of the Drawings:

Page 8, line 14, before "sample" insert --a--.

In the Description of the Invention:

Page 10, line 3, after "physician" insert ---.

Page 25, line 3, was incorrectly amended to place two commas after "interrogation" and no commas after "programming". The line to read correctly should have one comma after "programming" and one comma after "interrogation".

Page 27, line 6, has been incorrectly amended so that the numeral "400" now appears twice after "unit". The numeral 400 should only appear once after "unit" on this line.

In the Claims:

Kindly cancel all claims presently in the application, without prejudice, and replace therefor the following new claims 85 through 726;

8. CM 1 ~~85~~ A programmable infusion system for providing medication to a living body <sup>of a patient</sup> comprising:

P<sub>1</sub> an infusion apparatus for implantation in said living body, said apparatus including

P<sub>2</sub> a medication reservoir for storing selected medication,

P<sub>2</sub> means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having at least one remotely commandable operational characteristic,

P<sub>2</sub> command receiver means coupled to said infusion means for receiving command signals, and

P<sub>2</sub> means for telemetering operational information pertaining to said infusion apparatus out of said living body;

D1 P<sub>1</sub> command source means external to said living body for transmitting said command signals to be received by said command receiver means; and

P<sub>1</sub> means for receiving said telemetered operational information external to said living body.

2  
1 ~~86~~ A programmable infusion system in accordance with claim ~~85~~, wherein one of said command signals transmitted by said command source means comprises a signal which corresponds to a selected operational rate at which said infusion means will infuse said selected medication into said living body.

3  
1 ~~87~~ A programmable infusion system in accordance with claim ~~85~~, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a plurality of operational medication dose inputs each

2  
corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected <sup>one of</sup> said medication dose <sup>inputs</sup> ~~input~~.

3 4  
88. A programmable infusion system in accordance with claim 87, wherein said infusion apparatus further comprises electronic control means coupled to said infusion means and said command receiver means, said ~~electric~~ <sup>electronic</sup> control means <sup>including means</sup> for maintaining a history of the infusion rate at which said infusion means has operated, said ~~electronic~~ <sup>including means</sup> control means for precluding the infusion of said selected medication by said infusion means if said rate requested by said patient programming unit exceeds a predetermined safe medication infusion rate based on said maintained history.

D1  
89. A programmable infusion system in accordance with claim 88, wherein said electronic control means is coupled to said telemetry means, said patient programming unit including means for indicating to said patient if said selected infusion rate exceeds said predetermined safe medication infusion rate, said ~~selective~~ <sup>electronic</sup> control means selectively sending a signal to said indicating means via said telemetry means and said telemetry receiving means, said telemetry receiving means being coupled to said indicating means.

3 6  
90. A programmable infusion system in accordance with claim 87, wherein said patient programming unit further comprises annunciator means and visual display means for providing information regarding previously selected medication infusion rates, for indicating whether a proper programming of a presently requested infusion rate has been communicated to said command receiver, and for selectively providing information as to the time and rate of previously selected medication infusion.

<sup>3</sup>  
91. A programmable infusion system in accordance with claim 85, further comprising means for selectively supplying power to said command receiver means, said supply means being coupled to an external power source, said supply means being external to said living body, said infusion means being powered by an implanted power source.

<sup>8</sup>  
92. A programmable infusion system, in accordance with claim 91, wherein said supply means provides an alternating field.

<sup>9</sup>  
93. A programmable infusion system, in accordance with claim 92, wherein said infusion apparatus further comprises detector means for detecting said alternating field and for converting the same into electrical energy, said detecting means being coupled to said command receiver.

D'  
<sup>10</sup>  
94. A programmable infusion system in accordance with claim 93, wherein said infusion apparatus further comprises means for rectifying said electrical energy into a d.c. power signal.

<sup>11</sup>  
95. A programmable infusion system in accordance with claim 94, wherein said d.c. power signal is coupled to said implanted power source to effect the charging thereof.

<sup>12</sup>  
10 96. A programmable infusion system in accordance with claim 94, wherein said telemetry means is coupled to said rectifier means and is powered by said d.c. power signal.

<sup>13</sup>  
97. A programmable infusion system in accordance with claim 91, wherein said telemetry means is also supplied power by said supply means.

<sup>14</sup>  
98. A programmable infusion system in accordance with claim 91, further comprising means for selectively recharging said implanted power source, said recharging means being powered by said supply means.

<sup>15</sup>  
99. A programmable infusion system in accordance with claim 85, wherein said infusion means comprises a fluid handling mechanism for delivering said selected medication, said operational information including information about the operation of said fluid handling mechanism.

<sup>16</sup>  
100. A programmable infusion system in accordance with claim 99, wherein said fluid handling mechanism comprises means for pumping said selected medication.

<sup>17</sup>  
101. A programmable infusion system in accordance with claim 100, wherein the amount of medication pumped by said pumping means is controlled by a pressure limit in said pump means.

<sup>18</sup>  
102. A programmable infusion system in accordance with claim 100, wherein said pump means operates in a pulsatile mode.

<sup>19</sup>  
103. A programmable infusion system in accordance with claim 102, wherein said pump means pumps a fixed volume of said selected medication each time said pump means is pulsed.

<sup>20</sup>  
104. A programmable infusion system in accordance with claim 100, wherein said pump means comprises variable volume means for storing said selected medication within said pump means, an increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, a decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.

Sub E2

105. A programmable infusion system in accordance with claim 104, wherein said variable volume means comprises at least one flexible wall, movement of said <sup>at least one</sup> flexible wall varying the volume of said variable volume means, and means for moving said <sup>at least one</sup> flexible wall.

N  
K  
N  
P  
D  
106. A programmable infusion system in accordance with claim 105, further comprising spring means for urging said <sup>at least one flexible</sup> wall in a manner which decreases the volume of said variable volume means, the magnitude of the force applied to and stored by said spring means increasing as the volume of said variable volume means increases due to the displacement of said <sup>at least one</sup> flexible wall thereof by said moving means.

107. A programmable infusion system in accordance with claim 106, wherein said <sup>at least one</sup> flexible wall comprises a bellows assembly having mounted on one end thereof a plate, the other end of said bellows <sup>assembly</sup> being in communication with said selected medication, the walls of said bellows <sup>assembly</sup> serving as said spring means.

24  
23 108. A programmable infusion system in accordance with claim 107, wherein said plate has a surface in contact with said selected medication when drawn into said variable volume means.

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25  
24 109. A programmable infusion system in accordance with claim 108, wherein said bellows <sup>assembly</sup> is inhibited from moving said plate when the pressure (p) in said variable volume means exceeds the spring force (F) of said bellows <sup>assembly</sup> divided by the wetted area (A) of said surface of said plate in contact with said selected medication, that is when  $p > \frac{F}{A}$ .

E  
26  
23 110. A programmable infusion system in accordance with claim 107, wherein <sup>said plate is magnetizable, comprising</sup> said moving means ~~comprises said plate being~~

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~~magnetisable~~ and a coil disposed proximate to said plate, said coil selectively radiating a pulsing magnetic field, pulsing of said coil causing said plate to be moved.

26 <sup>27</sup>  
111. A programmable infusion system in accordance with claim 110, wherein said plate comprises a permanent magnet.

23 <sup>28</sup>  
112. A programmable infusion system in accordance with claim 107, further comprising means for limiting the distance said plate can move in both <sup>a a</sup> ~~the~~ volume increasing direction and <sup>a a</sup> ~~the~~ volume decreasing direction.

20 <sup>29</sup>  
113. A programmable infusion system in accordance with claim 104, wherein said infusion means further comprises:

E ~  
D'  
P<sub>i</sub> an interface pressure <sup>valve</sup> ~~valve~~ through which said selected medication enters said variable volume means from said medication reservoir, said interface pressure valve being normally closed;

P<sub>i</sub> an outlet chamber which is in communication with said living body; and

P<sub>i</sub> an outlet pressure valve located between said variable volume means and said outlet chamber, said outlet pressure valve being normally closed, an increase in volume of said variable volume means causing said interface pressure valve to open and medication to enter said variable volume means, a decrease in volume of said variable volume means causing said outlet pressure valve to open and said interface pressure valve to close, so as to permit medication to enter said outlet chamber as a pressure pulse.

24 <sup>30</sup>  
114. A programmable infusion system in accordance with claim 113, wherein said outlet chamber comprises an elastic wall having a fluidic capacitive effect on the flow of said selected

medication and a filter element through which liquid flow to the  
said ~~living~~<sup>living</sup> body is resisted, said elastic wall and said filter  
comprising a fluid resistance - capacitance arrangement with  
respect to said flow of said selected medication from said  
outlet chamber into said living body.

19 31  
102 115. A programmable infusion system in accordance with claim  
102, further comprising means for feeding said selected  
medication into said living body from said pump means in a flow  
which decays exponentially over time.

32  
116. A programmable infusion system in accordance with claim  
31, wherein said feeding means comprises a mechanical  
resistance (R) and a mechanical capacitance (C) circuit  
resulting in an exponentially decaying outflow of medication for  
each said fixed volume pulse.

33  
26 117. A programmable infusion system in accordance with claim  
104, wherein said infusion means further comprises an outlet  
chamber which is in communication with said living body, said  
pump means expelling said selected medication into said outlet  
chamber, and means for monitoring the operation of said pump  
means, said monitoring means being disposed in said outlet  
chamber and providing a signal in response to a pressure pulse  
in said outlet chamber caused by said pump means, said  
monitoring means being operably coupled to said telemetry means.

34  
33 118. A programmable infusion system in accordance with claim  
117, wherein said monitoring means comprises a pressure  
transducer.

35  
33 119. A programmable infusion system in accordance with claim  
117, further comprising first means for indicating the operation



of said pump means when a decrease in volume of said variable volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

8 36  
112 120. A programmable infusion system in accordance with claim 119, further comprising second means for indicating the operation of said pump means when a signal is provided by said monitoring means absent a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

116 37  
121. A programmable infusion system in accordance with claim 120, further comprising means for monitoring the operation of said pump means, said monitoring means being operably coupled to said telemetry means.

38  
37 122. A programmable infusion system in accordance with claim 121, wherein said monitoring means comprises pressure sensing means disposed in the path of flow of said selected medication into said living body, said pressure sensing means providing a signal in response to a pressure pulse in said path of flow.

39 on  
Sub E 3  
YELLOW  
N  
K  
E  
P  
123. A programmable infusion system in accordance with claim 122, further comprising first means for indicating the operation of said pump means when a decrease in volume of said variable volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

parallel claim 119

E 240

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39 124

124. A programmable infusion system in accordance with claim 123, further comprising second means for indicating the operation of said pump means when a signal is provided by said monitoring means absent a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

E 241

41  
1 125

125. A programmable infusion system in accordance with claim 125, wherein one of said <sup>at least one</sup> remotely commandable operational ~~characteristic~~ <sup>characteristics</sup> comprises an infusion rate variable on command, said infusion apparatus further comprising means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded by a commanded infusion rate, said inhibiting means being operably coupled to said infusion means.

D1

42  
41 126

126. A programmable infusion system in accordance with claim 125, wherein said inhibiting means comprises at least one means for defining a fixed infusion rate limit.

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43  
42 127

127. A programmable infusion system in accordance with claim 126, wherein said <sup>at least one</sup> means for defining a fixed infusion rate limit is hardwired.

44  
41 128

128. A programmable infusion system in accordance with claim 125, wherein said preselected medication infusion rate is remotely selectable.

45  
41 129

129. A programmable infusion system in accordance with claim 125, wherein said preselected medication infusion rate comprises a remotely selectable rate and a fixed rate, said remotely selectable rate being limited by said fixed rate.

CLAIM 46  
43

Sub E4

130. A programmable infusion system in accordance with claim 129, wherein said inhibiting means comprises:

at least one programmable rate memory unit coupled to said command receiver means, each of said programmable rate memory units for receiving and storing an infusion rate input command corresponding to said remotely selectable rate;

at least one limit control unit each of which provides a fixed rate limit; and

means for comparing each of said infusion rate input commands to a corresponding said fixed rate limit, infusion of said medication at a rate exceeding said fixed rate limit being inhibited.

47  
D'E 46 131. A programmable infusion system in accordance with claim 130, further comprising command decoder means for coupling <sup>each of</sup> said <sup>units</sup> at least one ~~said~~ programmable rate memory ~~unit~~ to said command receiver means, said command decoder means for decoding said command signals received by said command receiver means into <sup>corresponding</sup> said infusion rate inputs for receipt by and storage <sup>in</sup> said at least one programmable rate memory <sup>units</sup> ~~unit~~.

48  
E 46 132. A programmable infusion system in accordance with claim 130, wherein each of said <sup>at least one</sup> limit control units <sup>is</sup> ~~are~~ hardwired.

49  
46 133. A programmable infusion system in accordance with claim 130, further comprising means for generating an alarm signal when any infusion rate input command exceeds a corresponding fixed rate limit.

50  
46 134. A programmable infusion system in accordance with claim 130, wherein said inhibiting means precludes infusion of said medication by said infusion means when the selected said

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commandable infusion rate exceeds said preselected medication  
infusion rate during a ~~fixed~~ <sup>of a predetermined length</sup> window of time which shifts  
continuously.

41 51  
125. A programmable infusion system in accordance with claim  
125, wherein said inhibiting means precludes infusion of said  
medication by said infusion means when the selected said  
commandable infusion rate <sup>preselected medication</sup> exceeds said ~~preselected~~ infusion rate  
during a ~~fixed~~ <sup>of a predetermined length</sup> window of time which shifts continuously.

CLAIMS  
52-54  
on  
Yellow  
DI  
N  
N  
N  
P  
136. A programmable infusion system in accordance with claim  
125, wherein said infusion means includes a pump means which  
executes in pulses, said inhibiting means comprising a  
programmable memory rate unit coupled to said command receiver  
for storing initially a <sup>local limit</sup> number corresponding to a first maximum  
number of infusion pulses preselected as allowable during a  
first shifting time window of a predetermined length, pulse  
quantities being subtracted from said number stored in said  
programmable memory rate unit as infusion pulses are executed by  
said infusion means, <sup>E</sup> pulse quantities being added to said stored  
number as time elapses such that said number does not exceed  
said first maximum number, said subtraction and addition being  
accomplished in running integral fashion, said inhibiting means  
not permitting pulsing of said pump means a number of times in  
excess of said number stored in said programmable memory rate  
unit.

53  
52-  
137. A programmable infusion system in accordance with claim  
136, wherein said memory rate unit also records the number of  
pulses which have been inhibited and causes said pump means of  
said infusion means to execute said pulses when said pulses can  
be subtracted from said number stored in said programmable  
memory rate unit as a result of the elapse of time.

N  
K  
N  
P  
DI

138. A programmable infusion system in accordance with claim 136, wherein said programmable memory rate unit also stores initially another <sup>dose limit</sup> number corresponding to a second maximum number of infusion pulses preselected as allowable during a second shifting time window of a predetermined length, said second shifting time window being longer in length than said first shifting time window, pulse quantities being subtracted from said another <sup>dose limit</sup> number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said another <sup>dose limit</sup> stored number as time elapses such that said another <sup>dose limit</sup> number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means <sup>+ a dose</sup> a number of times in excess of said another <sup>dose limit</sup> number stored in said programmable memory rate unit.

E

<sup>55</sup>  
~~54~~ 139. A programmable infusion system in accordance with claim 138, wherein said rate memory unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted from said <sup>both dose limit</sup> numbers stored in said programmable memory rate unit.

<sup>56</sup>  
~~55~~ 140. A programmable infusion system in accordance with claim 139, wherein said inhibiting means further comprises at least one fixed infusion rate limit which limits the total maximum infusion rate of said infusion means.

<sup>57</sup>  
~~56~~ 141. A programmable infusion system in accordance with claim 140, wherein said fixed infusion rate limit is hardwired.

49

<sup>58</sup>  
~~142~~. A programmable infusion system in accordance with claim  
<sup>54</sup>  
~~138~~, further comprising means for generating an alarm signal  
when any commanded infusion rate results in the inhibiting of  
pulsing of said pump means by said inhibiting means.

<sup>59</sup>  
<sup>58</sup>  
~~142~~. A programmable infusion system in accordance with claim  
~~142~~, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

<sup>60</sup>  
<sup>54</sup>  
~~138~~. A programmable infusion system in accordance with claim  
~~138~~, further comprising command decoder means for coupling said  
command receiver means to said programmable memory rate unit,  
said command decoder means for decoding said command signals  
received by said command receiver means into said first and  
<sup>maximum</sup>  
second numbers of infusion pulses.

<sup>61</sup>  
<sup>41</sup>  
~~125~~. A programmable infusion system in accordance with claim  
~~125~~, wherein said inhibiting means is operably coupled to said  
telemetry means, said inhibiting means providing a signal to  
said telemetry means for telemetering to said telemetry  
receiving means operational information pertaining to the  
functions of said inhibiting means.

<sup>62</sup>  
<sup>41</sup>  
~~125~~. A programmable infusion system in accordance with claim  
~~125~~, further comprising means for generating an alarm signal  
when said inhibiting means inhibits said infusion means.

<sup>63</sup>  
<sup>41</sup>  
~~125~~. A programmable infusion system in accordance with claim  
~~125~~, further comprising means for recording when said inhibiting  
means inhibits said infusion means.

<sup>64</sup>  
<sup>63</sup>  
~~147~~. A programmable infusion system in accordance with claim  
~~147~~, wherein said recording means is coupled to said telemetry

means, said recording means providing a signal to said telemetry means for telemetering to said telemetry receiving means operational information pertaining to said inhibiting means as recorded by said recording means.

65  
149. A programmable infusion system in accordance with claim 85, said infusion apparatus further comprising means for generating a distinctive alarm signal pattern for each of a plurality of improper <sup>operational</sup> operation conditions.

Sub E6  
CLAIMS  
66-78  
FELLOW  
174-175  
150. A programmable infusion system in accordance with claim 149, wherein said alarm signal is delivered to said living body subcutaneously.

D1  
11-23  
N  
K  
N  
P  
11-22  
151. A programmable infusion system in accordance with claim 150, further comprising means for detecting a medication leak, coupled to said alarm means, wherein one of said improper operation conditions comprises a medication leak out of said medication reservoir.

152. A programmable infusion system in accordance with claim 150, further comprising means for detecting a body fluid leak, coupled to said alarm means, wherein one of said improper operation conditions comprises a leak of body fluids into said infusion apparatus.

153. A programmable infusion system in accordance with claim 150, further comprising means for detecting the rate at which said infusion means is operating, coupled to said alarm means, wherein one of said improper operation conditions comprises operation of said infusion means at an improper rate.

154. A programmable infusion system in accordance with claim 150, wherein one of said improper operation conditions comprises receiving of a command by said command receiver which cannot be executed.

155. A programmable infusion system in accordance with claim 150, further comprising battery means for powering said infusion means and means for determining the voltage of said battery coupled to said alarm means, wherein one of said improper operation conditions comprises low battery voltage.

156. A programmable infusion system in accordance with claim 150, further comprising means for detecting the amount of medication disposed in said reservoir coupled to said alarm means, wherein one of said improper operation conditions comprises a preselected amount of medication remaining in said medication reservoir.

157. A programmable infusion system in accordance with claim 149, further comprising means for detecting a medication leak coupled to said alarm means, wherein one of said improper operation conditions comprises a medication leak out of said medication reservoir.

158. A programmable infusion system in accordance with claim 149, further comprising means for detecting a body fluid leak coupled to said alarm means, wherein one of said improper operation conditions comprises a leak of body fluids into said infusion apparatus.

159. A programmable infusion system in accordance with claim 149, further comprising means for detecting the rate at which said infusion means is operating coupled to said alarm means,



wherein one of said improper operation conditions comprises operation of said infusion means at an improper rate.

160. A programmable infusion system in accordance with claim 149, wherein one of said improper operation conditions comprises receiving of a command by said command receiver which cannot be executed.

161. A programmable infusion system in accordance with claim 149, further comprising battery means for powering said infusion means and means for determining the voltage of said battery, coupled to said alarm means wherein one of said improper operation conditions comprises low battery voltage.

162. A programmable infusion system in accordance with claim 149, further comprising means for detecting the amount of medication disposed in said reservoir coupled to said alarm means, wherein one of said improper operation conditions comprises a preselected amount of medication remaining in said medication reservoir.

163. A programmable infusion system in accordance with claim 149, further comprising means for simulating said improper operational conditions for test purposes.

164. A programmable infusion system in accordance with claim 149, wherein said infusion means includes means for pumping a preselected amount of medication into said living body, said infusion apparatus further comprising means for recording the rate at which pumping is effected by said pumping means.

165. A programmable infusion system in accordance with claim 164, wherein said recording means comprises:

means for storing the rate at which said ~~pumping~~ means pumps over a preselected time period;

means for storing a programmable input corresponding to a minimum medication infusion rate; and

means for comparing the rate recorded by said recording means to the rate stored in said ~~storing~~ means.

166. A programmable infusion system in accordance with claim 165, further comprising means for providing an alarm signal when said rate recorded by said recording means is less than said minimum medication infusion rate.

83  
81 ~~167~~. A programmable infusion system in accordance with claim ~~165~~, wherein said recording means is coupled to said telemetry means for telemetering information ~~deduced~~ <sup>recorded</sup> by said recording means out of said living body.

84  
80 ~~168~~. A programmable infusion system in accordance with claim ~~164~~, wherein said recording means comprises:  
P<sub>1</sub> means for storing the rate at which said ~~pumping~~ <sup>pump</sup> means pumps over a preselected time period; and  
P<sub>1</sub> means for storing the rate at which said ~~pumping~~ <sup>pump</sup> means is signalled to pump over said preselected time period.

85  
84 ~~169~~. A programmable infusion system in accordance with claim ~~166~~, further comprising means for comparing the rates recorded by both said storing means.

86  
85 ~~170~~. A programmable infusion system in accordance with claim ~~169~~, wherein said comparing means is coupled to said telemetry means for telemetering information ~~deduced~~ <sup>outputted</sup> by said comparing means out of said living body.

87  
85 171. A programmable infusion system in accordance with claim  
169, further comprising means for providing an alarm signal when  
the rate at which said <sup>pump</sup> ~~pumping~~ means pumps is different than the  
rate at which said <sup>pump 1</sup> ~~pumping~~ means <sup>is</sup> ~~if~~ signalled to pump.

88  
84 172. A programmable infusion system in accordance with claim  
168, wherein said recording means is coupled to said telemetry  
means for telemetering information recorded by ~~both~~ said  
recording means out of said living body.

89  
80 173. A programmable infusion system in accordance with claim  
164, wherein said pump means executes in pulses, said recording  
means comprising a pulse rate detector comprising:

P<sub>1</sub> means for counting the number of times said ~~pumping~~ means  
pumps over a preselected time period, said counting means  
storing the count;

P<sub>1</sub> minimum rate memory means for storing a programmable number  
input corresponding to a minimum medication infusion rate; and

P<sub>1</sub> means for comparing the number counted by said counting  
means with said programmable number input stored in said minimum  
rate memory means.

90  
89 174. A programmable infusion system in accordance with claim  
173, further comprising means for providing an alarm signal when  
said count is less than said programmable number input stored in  
said minimum rate memory means.

91  
90 175. A programmable infusion system in accordance with claim  
174, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

92  
90 176. A programmable infusion system in accordance with claim  
174, wherein said counting means comprises a pressure  
transducer.

93  
87 177. A programmable infusion system in accordance with claim  
173, wherein said comparing means is coupled to said telemetry  
means for telemetering information <sup>outputted</sup> ~~deduced~~ by said comparing  
means out of said living body.

94  
80 178. A programmable infusion system in accordance with claim  
164, wherein said pump means executes in pulses, said recording  
means comprising a pulse recorder comprising:

E P<sub>1</sub> means for counting the number of times said <sup>pump</sup> ~~pumping~~ means  
pumps over a preselected time period, said counting means  
storing the count; and

E P<sub>1</sub> means for counting the number of times said <sup>pump</sup> ~~pumping~~ means is  
commanded to pump over said preselected time period.

D1  
95  
E 179. A programmable infusion system in accordance with claim  
178, wherein said pulse recorder further comprises means for  
comparing the <sup>numbers</sup> ~~number~~ recorded by both said counting means.

96  
95 180. A programmable infusion system in accordance with claim  
179, wherein said comparing means is coupled to said telemetry  
means for telemetering information <sup>outputted</sup> ~~deduced~~ by said comparing  
means out of said living body.

97  
94 181. A programmable infusion system in accordance with claim  
178, further comprising means for providing an alarm signal when  
said numbers recorded by both said counting means are different.

98  
92 182. A programmable infusion system in accordance with claim  
181, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

<sup>99</sup>  
~~94~~ 183. A programmable infusion system in accordance with claim  
~~178~~, wherein said recording means is coupled to said telemetry  
means for telemetering information recorded by both said  
counting means out of said living body.

<sup>186</sup>  
~~94~~ 184. A programmable infusion system in accordance with claim  
~~178~~, wherein said first recited counting means comprises a  
pressure transducer.

E <sup>101</sup>  
1 185. A programmable infusion system in accordance with claim  
~~85~~, further comprising means for maintaining the pressure within  
said medication reservoir at a pressure level below the internal  
pressure of said living body.

D' <sup>102</sup>  
~~101~~ 186. A programmable infusion sytem in accordance with claim  
~~185~~, wherein said pressure maintaining means comprises:  
R a flexible diaphragm which divides said medication reservoir  
into a medication chamber and a liquid-vapor pool chamber; and  
R a liquid vapor pool disposed within said liquid-vapor pool  
chamber, the proportion of liquid to vapor in said liquid-vapor  
pool varying in response to variations in the amount of said  
selected medication disposed in said medication chamber.

<sup>103</sup>  
~~102~~ 187. A programmable infusion system in accordance with claim  
~~186~~, said infusion apparatus further comprising switch means  
disposed within said medication reservoir, said switch means  
being coupled to said telemetry means and being activated when  
said flexible diaphragm is disposed in a preselected  
relationship relative to said switch means, said telemetry means  
telemetering a signal indicative of such an operational  
condition to said telemetry receiving means.

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<sup>104</sup>  
E. <sup>103</sup>~~188~~. A programmable infusion system in accordance with claim  
~~187~~, wherein said switch means is activated by pressure exerted  
thereon by said flexible diaphragm, said pressure being less  
than the ambient pressure of said body.

<sup>105</sup>  
E. <sup>102</sup>~~189~~. A programmable infusion system in accordance with claim  
~~188~~, said infusion apparatus further comprising an antechamber  
through which access is gained to said medication reservoir, and  
a reservoir inlet valve located between said antechamber and  
said medication chamber, said reservoir inlet valve being  
operable ~~and~~ when the pressure in said antechamber exceeds the  
pressure in <sup>said medication</sup> ~~the reservoir~~ chamber by more than a predetermined  
differential.

<sup>106</sup>  
D' <sup>105</sup>~~190~~. A programmable infusion system in accordance with claim  
~~189~~, wherein the volume of said antechamber is less than 10% the  
volume of said <sup>medication</sup> ~~reservoir~~ chamber.

<sup>107</sup>  
<sup>105</sup>~~191~~. A programmable infusion system in accordance with claim  
~~189~~, further comprising an inlet filter means operably disposed  
between said antechamber and said medication chamber for  
preventing impurities in said selected medication in said  
antechamber from passing into said medication chamber when said  
reservoir inlet valve is opened, said filter means also  
preventing said selected medication in said medication chamber  
from rapidly entering said living body in the event of a leak in  
said inlet valve.

<sup>108</sup>  
L. <sup>108</sup>~~192~~. A programmable infusion system in accordance with claim  
~~191~~, further comprising means for programmed pumping of  
fixed-volume pulses of medication into said living body.

61

109  
193. A programmable infusion system in accordance with claim 93, further comprising means for injecting medication into said medication reservoir, said injecting means being coupled to said telemetering receiver means, and programming means coupled to said <sup>telemetry</sup> ~~telemetering~~ means for indicating when ejection of medication into said medication reservoir is appropriate.

110  
194. A programmable infusion system for providing medication to a living body <sup>of a patient</sup> comprising;

P<sub>1</sub> an infusion apparatus for implantation in said living body, said apparatus including

P<sub>2</sub> a medication reservoir for storing selected medication,  
P<sub>2</sub> means for infusion said selected medication stored in said medication reservoir into said living body, said infusion means having at least one remotely commandable operational characteristic and being powered by an implanted power source,

P<sub>2</sub> command receiver means coupled to said infusion means for receiving command signals, said command receiver means being powered by a power source external to said living body, and

P<sub>2</sub> means for telemetering operational information pertaining to said infusion apparatus out of said living body;

K command source means external to said living body for transmitting said command signals to be received by said command receiver means;

P<sub>1</sub> means for receiving said telemetered operational information external to said living body; and

P<sub>1</sub> means for selectively supplying power to said command receiver means, said supply means being coupled to said external power source, said supply means being external to said living body.

<sup>111</sup>  
~~118~~ 193. A programmable infusion system in accordance with claim  
~~194~~, wherein said supply means provides an alternating field.

<sup>112</sup>  
~~111~~ 196. A programmable infusion system in accordance with claim  
~~195~~, wherein said infusion apparatus further comprises detector  
means for detecting said alternating field and for converting  
the same into electrical energy, said detecting means being  
coupled to said command receiver.

<sup>113</sup>  
~~112~~ 197. A programmable infusion system in accordance with claim  
~~196~~, wherein said infusion apparatus further comprises means for  
rectifying said electrical energy into a d.c. power signal.

<sup>114</sup>  
~~113~~ 198. A programmable infusion system in accordance with claim  
~~197~~, wherein said d.c. power signal is coupled to said implanted  
power source to effect the charging thereof.

<sup>115</sup>  
~~113~~ 199. A programmable infusion system in accordance with claim  
~~197~~, wherein said telemetry means is coupled to said rectifier  
means and is powered by said d.c. power signal.

<sup>116</sup>  
~~110~~ 200. A programmable infusion system in accordance with claim  
~~194~~, wherein said <sup>telemetry</sup> ~~telemetry~~ means is also supplied power by  
said supply means.

<sup>117</sup>  
~~110~~ 201. A programmable infusion system in accordance with claim  
~~194~~ further comprising means for selectively recharging said  
implanted power source, said recharging means being powered by  
said supply means.

<sup>118</sup>  
~~110~~ 202. A programmable infusion system in accordance with claim  
~~194~~, wherein one of said command signals transmitted by said  
command source means comprises a signal which corresponds to a



selected operational rate at which said infusion means will infuse said selected medication into said living body.

<sup>119</sup>  
~~110~~ 203. A programmable infusion system in accordance with claim ~~194~~, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a plurality of operational medication dose inputs each corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected said medication dose <sup>one of</sup> ~~input~~ <sup>inputs</sup> ~~input~~.

<sup>120</sup>  
~~119~~ 204. A programmable infusion system in accordance with claim ~~203~~, wherein said infusion apparatus further comprises electronic control means coupled to said infusion means and said command receiver means, said electronic control means <sup>including means</sup> for maintaining a history of the infusion rate at which said infusion means has operated, said electronic control means <sup>including means</sup> for precluding the infusion of said selected medication of said infusion means if said rate requested by said patient programming unit exceeds a predetermined safe medication infusion rate based on said maintained history.

<sup>121</sup>  
~~120~~ 205. A programmable infusion system in accordance with claim ~~204~~, wherein said electronic control means is coupled to said telemetry means, said patient programming unit including means for indicating to said patient if said selected infusion rate exceeds said predetermined safe medication infusion rate, said <sup>electronic</sup> ~~selective~~ control means selectively sending a signal to said indicating means via said telemetry means and said telemetry receiving means, said telemetry receiving means being coupled to said indicating means.

119-122  
206. A programmable infusion system in accordance with claim  
205, wherein said patient programming unit further comprises  
annunciator means and visual display means for providing  
information regarding previously selected medication infusion  
rates, for indicating whether a proper programming of a  
presently requested infusion rate has been communicated to said  
command receiver, and for selectively providing information as  
to the time and rate of previously selected medication infusion.

123  
170-207. A programmable infusion system in accordance with claim  
194, wherein said infusion means comprises a fluid handling  
mechanism for delivering said selected medication, said  
operational information including information about the  
operation of said fluid handling mechanism.

01 124  
123-208. A programmable infusion system in accordance with claim  
207, wherein said fluid handling mechanism comprises means for  
pumping said selected medication.

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increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, a decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.

Sub E9

213. A programmable infusion system in accordance with claim 212, wherein said variable volume means comprises at least one flexible wall, movement of said <sup>at least one</sup> flexible wall varying the value of said variable volume means, and means for moving said <sup>at least one</sup> flexible wall.

214. A programmable infusion system in accordance with claim 213, further comprising spring means for urging said <sup>at least one</sup> wall in a manner which decreases the volume of said variable volume means, the magnitude of the force applied to and stored by said spring means increasing as the volume of said variable volume means increases due to the displacement of said <sup>at least one</sup> flexible wall thereof by said moving means.

215. A programmable infusion system in accordance with claim 214, wherein said flexible wall comprises a bellows assembly having mounted on one end thereof a plate, the other end of said bellows being in communication with said selected medication, the walls of said bellows serving as said spring means.

<sup>131</sup>  
~~215~~ 216. A programmable infusion system in accordance with claim <sup>137</sup> 215, wherein said plate has a surface in contact with a said selected medication when drawn into said variable volume means. ✓

<sup>133</sup>  
<sup>136</sup> 217. A programmable infusion system in accordance with claim <sup>136</sup> 216, wherein said bellows <sup>assembly</sup> is inhibited from moving said plate when the pressure (p) in said <sup>variable</sup> volume means exceeds the spring force (F) of said bellows <sup>assembly</sup> divided by the wetted area (A)

$\epsilon$  of said surface of said plate in <sup>contact</sup> with said selected medication, that is when  $p > \frac{F}{A}$ .

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218. A programmable infusion system in accordance with claim 215, wherein said moving means comprises said plate being magnetizable and a coil disposed proximate to said plate, said coil selectively radiating a pulsing magnetic field, pulsing of said coil causing said plate to be moved.

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134 219. A programmable infusion system in accordance with claim 218, wherein said plate comprises a permanent magnet.

136  
131 220. A programmable infusion system in accordance with claim 215, further comprising means for limiting the distance said plate can move in both <sup>the</sup> ~~the~~ volume increasing direction and <sup>the</sup> ~~the~~ volume decreasing direction.

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128 221. A programmable infusion system in accordance with claim 212, wherein said infusion means further comprises:

P<sub>1</sub> an interface pressure valve through which said selected medication enters said variable volume means from said medication reservoir, said interface pressure valve being normally closed;

222 P<sub>1</sub> an outlet chamber which is in communication with said living body; and

$\epsilon$  P<sub>1</sub> an outlet pressure valve located between said variable volume means and said outlet chamber, said outlet pressure <sup>valve</sup> ~~value~~ being normally closed, an increase in volume of said variable volume means causing said interface pressure valve to open and medication to enter said variable volume means, a decrease in volume of said variable volume means causing said outlet pressure <sup>valve</sup> ~~value~~ to open and said interface pressure valve to

close, so as to permit medication to enter said outlet chamber as a pressure pulse.

<sup>138</sup>  
~~137~~ 222. A programmable infusion system in accordance with claim ~~221~~, wherein said outlet chamber comprises an elastic wall having a fluidic capacitive effect on the flow of said selected medication and a filter element through which liquid flow to the said living body is resisted, said elastic wall and said filter comprising a fluid resistance-capacitance arrangement with respect to said flow of said selected medication from said outlet chamber into said living body.

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<sup>139</sup>  
~~137~~ 223. A programmable infusion system in accordance with claim ~~211~~, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.

<sup>140</sup>  
~~139~~ 224. A programmable infusion system in accordance with claim ~~223~~, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.

<sup>141</sup>  
~~139~~ 225. A programmable infusion system in accordance with claim ~~208~~, wherein said infusion means further comprises an outlet chamber which is in communication with said living body, said pump means expelling said selected medication into said outlet chamber, ~~means~~ and means for monitoring the operation of said pump means, said monitoring means being disposed in said outlet chamber and providing a signal in response to a pressure pulse in said outlet chamber caused by said pump means, said monitoring means being operably coupled to said telemetry means.

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226. A programmable infusion system in accordance with claim  
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225, wherein said monitoring means comprises a pressure  
transducer.

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227. A programmable infusion system in accordance with claim  
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225, further comprising first means for indicating the operation  
of said pump means when a decrease in volume of said variable  
volume means is not followed by a signal from said monitoring  
means corresponding to a pressure pulse of said selected  
medication expelled into said outlet chamber, said first  
indicating means being operably coupled to said telemetry means.

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228. A programmable infusion system in accordance with claim  
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227, further comprising second means for indicating the  
operation of said pump means when a signal is provided by said  
monitoring means absent a decrease in volume of said variable  
volume means ~~caused by said moving means~~, said second indicating  
means being operably coupled to said telemetry means.

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229. A programmable infusion system in accordance with claim  
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208, further comprising means for monitoring the operation of  
said pump means, said monitoring means being operably coupled to  
said telemetry means.

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230. A programmable infusion system in accordance with claim  
145  
229, wherein said monitoring means comprises pressure sensing  
means disposed in the path of flow of said selected <sup>medication</sup> medication  
into said <sup>living</sup> living body, said pressure sensing means providing a  
signal in response to a pressure pulse in said path of flow.

CLAIM 211  
147 on  
231. A programmable infusion system in accordance with claim  
230, further comprising first means for indicating the operation  
of said pump means when a decrease in volume of said variable

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volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

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232. A programmable infusion system in accordance with claim 231, further comprising second means for indicating the operation of said pump means when a signal is provided by said monitoring means absent a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

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233. A programmable infusion system in accordance with claim 194, wherein one of said <sup>at least one</sup> remotely commandable operational characteristics comprises an infusion rate variable on command, said infusion apparatus further comprising means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded by a commanded infusion rate, said inhibiting means being operably coupled to said infusion means.

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234. A programmable infusion system in accordance with claim 233, wherein said inhibiting means comprises at least one means for defining a fixed infusion rate limit.

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235. A programmable infusion system in accordance with claim 234, wherein said <sup>at least one</sup> means for defining a fixed infusion rate limit is hardwired.

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236. A programmable infusion system in accordance with claim 235 wherein said preselected medication infusion rate is remotely selectable.

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153  
237. A programmable infusion system in accordance with claim  
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233, wherein said preselected medication infusion rate comprises  
a remotely selectable rate and a fixed rate, said remotely  
selectable rate being limited by said fixed rate.

CUA 152  
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238. A programmable infusion system in accordance with claim  
237, wherein said inhibiting means comprises:

at least one programmable rate memory unit coupled to said  
command receiver means, each of said programmable rate memory  
units for receiving and storing an infusion rate input command  
corresponding to said remotely selectable rate;

at least one limit control unit each of which provides a  
fixed rate limit; and

means for comparing each of said infusion rate input  
commands to a corresponding said fixed rate limit, infusion of  
said medication at a rate exceeding said fixed rate limit being  
inhibited.

239. A programmable infusion system in accordance with claim  
238, further comprising command decoder means for coupling said  
at least one said programmable rate memory limit to said command  
receiver means, said command decoder means for decoding said  
command signals received by said command receiver means into  
said infusion rate inputs for receipt by and storage in said at  
least one programmable rate memory unit.

240. A programmable infusion system in accordance with claim  
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238, wherein each of said limit control units <sup>at least one</sup> ~~is~~ <sup>is</sup> ~~are~~ hardwired.

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241. A programmable infusion system in accordance with claim  
238, further comprising means for generating an alarm signal  
when any infusion rate input command exceeds a corresponding  
fixed rate limit.

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157 158  
242. A programmable infusion system in accordance with claim  
238, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

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243. A programmable infusion system in accordance with claim  
238, wherein said inhibiting means precludes infusion of said  
medication by said infusion means when the selected said  
commandable infusion rate exceeds said preselected medication  
infusion rate during a ~~fixed~~ <sup>of a predetermined length</sup> window of time, which shifts  
continuously.

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244. A programmable infusion system in accordance with claim  
233, wherein said inhibiting means precludes infusion of said  
medication <sup>by</sup> said infusion means when the selected said  
commandable infusion rate exceeds said preselected medication  
infusion rate during a ~~fixed~~ <sup>of a predetermined length</sup> window of time, which shifts  
continuously.

CLAIM 8132  
161-164 on  
follow  
245. A programmable infusion system in accordance with claim  
233, wherein said infusion means includes a pump means which  
executes in pulses, said inhibiting means comprising a  
programmable memory rate unit coupled to said command receiver  
for storing initially a <sup>first value</sup> number corresponding to a first maximum  
number of infusion pulses preselected as allowable during a  
first shifting time window of a predetermined length, pulse  
quantities being subtracted from said number stored in said  
programmable memory rate unit as infusion pulses are executed by  
said infusion means, pulse quantities being added to said stored  
number as time elapses such that said number does not exceed  
said first maximum number, said subtraction and addition being  
accomplished in running integral fashion, said inhibiting means  
not permitting pulsing of said pump means <sup>at a rate</sup> a number of times in  
excess of said number stored in said programmable memory rate  
unit.

246. A programmable infusion system in accordance with claim 245, wherein said memory rate unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted from said <sup>first limit</sup> number stored in said programmable memory rate unit as a result of the elapse of time.

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247. A programmable infusion system in accordance with claim 245, wherein said programmable memory rate unit also stores initially another <sup>second limit</sup> number corresponding to a second maximum number of infusion pulses preselected as allowable during a second shifting time window of a predetermined length, said second shifting time window being longer in length than said first shifting time window, pulse quantities being subtracted in ~~fixed running integral~~ fashion from said another number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said second number as time elapses such that said another <sup>second limit</sup> number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means at a <sup>rate</sup> ~~number~~ of times in excess of said another number stored in said programmable memory rate unit.

248. A programmable infusion system in accordance with claim 247, wherein said rate memory unit also records the number of pulses which have been inhibited and causes said infusion means to execute said pulses when said pulses can be subtracted from said <sup>unit</sup> numbers stored in said programmable memory rate unit.

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249. A programmable infusion system in accordance with claim 248, wherein said inhibiting means further comprises at least one fixed infusion rate limit which limits the total maximum infusion rate of said infusion means.

<sup>166</sup>  
~~165~~ 250. A programmable infusion system in accordance with claim  
~~249~~, wherein said fixed infusion rate limit is hardwired.

<sup>167</sup>  
~~163~~ 251. A programmable infusion system in accordance with claim  
~~247~~, further comprising means for generating an alarm signal  
when any commanded infusion rate results in the inhibiting of  
pulsing of said pump means by said inhibiting means.

<sup>168</sup>  
~~167~~ 252. A programmable infusion system in accordance with claim  
~~251~~, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

<sup>169</sup>  
~~165~~ 253. A programmable infusion system in accordance with claim  
~~247~~, further comprising command decoder means for coupling said  
command receiver means to said programmable memory rate unit,  
said command decoder means for decoding said command signals  
received by said command receiver means into said first and  
<sup>maximum</sup>  
second numbers of infusion pulses.

<sup>170</sup>  
~~149~~ 254. A programmable infusion system in accordance with claim  
~~233~~, wherein said inhibiting means is operably coupled to said  
telemetry means, said inhibiting means providing a signal to  
said telemetry means for telemetering to said telemetry  
receiving means operational information pertaining to the  
functions of said inhibiting means.

<sup>171</sup>  
~~149~~ 255. A programmable infusion system in accordance with claim  
~~233~~, further comprising means for generating an alarm signal  
when said inhibiting means inhibits said infusion means.

<sup>172</sup>  
~~149~~ 256. A programmable infusion system in accordance with claim  
~~233~~, further comprising means for recording when said inhibiting  
means inhibits said infusion means.

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257. A programmable infusion system in accordance with claim 233, wherein said recording means is coupled to said telemetry means, said recording means providing a signal to said telemetry means for telemetering to said telemetry receiving means operational information pertaining to said inhibiting means as recorded by said recording means.

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258. A programmable infusion system in accordance with claim 194, said infusion apparatus further comprising means for generating a distinctive alarm signal pattern for each of a plurality of improper <sup>operational</sup> operation conditions.

Sub E  
CLAIMS  
175-189  
D 1 on  
YELLOW  
259. A programmable infusion system in accordance with claim 258, wherein said alarm signal is delivered to said living body subcutaneously.

260. A programmable infusion system in accordance with claim 259, further comprising means for detecting a medication leak, coupled to said alarm <sup>operating</sup> means, wherein one of said improper operation conditions comprises a medication leak out of said medication reservoir.

261. A programmable infusion system in accordance with claim 259, further comprising means for detecting a body fluid leak, coupled to said alarm means wherein one of said improper operation conditions comprises a leak of body fluids into said infusion apparatus.

262. A programmable infusion system in accordance with claim 259, further comprising means for detecting the rate at which said infusion means is operating coupled to said alarm means, wherein one of said improper operation conditions comprises operation of said infusion means at an improper rate.

263. A programmable infusion system in accordance with claim 259, wherein one of said improper operation conditions comprises receiving of a command by said command receiver, which cannot be executed.

11/2/86  
(see claim 14)  
264. A programmable infusion system in accordance with claim 259, further comprising battery means for powering said infusion means and means for determining the voltage of said battery, coupled to said alarm, means wherein one of said improper operation conditions comprises low battery voltage.

11/2/86  
(see claim 14)  
D 1  
265. A programmable infusion system in accordance with claim 259, further comprising means for detecting the amount of medication disposed in said reservoir, coupled to said alarm means, wherein one of said improper operation conditions comprises a preselected amount of medication remaining in said medication reservoir.

11/2/86  
266. A programmable infusion system in accordance with claim 258, further comprising means for detecting a medication leak, coupled to said alarm means, wherein one of said improper operation conditions comprises a medication leak out of said medication reservoir.

11/2/86  
267. A programmable infusion system in accordance with claim 258, further comprising means for detecting a body fluid leak, coupled to said alarm means, wherein one of said improper operation conditions comprises a leak of body fluids into said infusion apparatus.

11/2/86  
268. A programmable infusion system in accordance with claim 258, further comprising means for detecting the rate at which said infusion means is operating, coupled to said alarm means,

wherein one of said improper operation conditions comprises operation of said infusion means at an improper rate.

269. A programmable infusion system in accordance with claim 258, wherein one of said improper operation conditions comprises receiving of a command by said command receiver which cannot be executed.

270. A programmable infusion system in accordance with claim 258, further comprising battery means for powering said infusion means and means for determining the voltage of said battery means coupled to said alarm means wherein one of said improper operation condition comprises low battery voltage.

271. A programmable infusion system in accordance with claim 258, further comprising means for detecting the amount of medication disposed in said reservoir coupled to said alarm means, wherein one of said improper operation conditions comprises a preselected amount of medication remaining in said medication reservoir.

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174 272. A programmable infusion system in accordance with claim 258, further comprising means for simulating said improper operational conditions for test purposes.

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110 273. A programmable infusion system in accordance with claim 258, wherein said infusion means includes means for pumping a preselected amount of medication into said living body, said infusion apparatus further comprising means for recording the rate at which pumping is effected by said pump means.

CLAIMS  
170-171  
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YELLOW  
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274. A programmable infusion system in accordance with claim 273, wherein said recording means comprises:

means for storing the rate at which said ~~pumping~~ means pumps over a preselected time period;

means for storing a programmable input corresponding to a minimum medication infusion rate; and

means for comparing the rate recorded by said recording means to the rate stored in said storing means.

275. A programmable infusion system in accordance with claim 274, further comprising means for providing an alarm signal when said rate recorded by said ~~recording~~ means is less than said minimum medication infusion rate.

191 192 276. A programmable infusion system in accordance with claim 274, wherein said recording means is coupled to said telemetry means for telemetering information ~~deduced~~ <sup>recorded</sup> by said recording means out of said living body.

189 193 277. A programmable infusion system in accordance with claim 275, wherein said recording means comprises:

P<sub>1</sub> means for storing the rate at which said ~~pumping~~ means pumps over a preselected time period; and

P<sub>1</sub> means for storing the rate at which said ~~pumping~~ means is signalled to pump over said preselected time period.

194 193 278. A programmable infusion system in accordance with claim 277, further comprising means for comparing the rates recorded by both said storing means.

195 194 279. A programmable infusion system in accordance with claim 278, wherein said comparing means is coupled to said telemetry means for telemetering information ~~deduced~~ <sup>outputted</sup> by said comparing means out of said living body.

196  
194 280. A programmable infusion system in accordance with claim  
278, further comprising means for providing an alarm signal when  
the rate at which said <sup>pump</sup> ~~pumping~~ means pumps is different than the  
rate at which said <sup>pump</sup> ~~pumping~~ means <sup>is</sup> ~~is~~ signalled to pump.

197  
193 281. A programmable infusion system in accordance with claim  
277, wherein said recording means is coupled to said telemetry  
means for telemetering information recorded by ~~both~~ said  
recording means out of said living body.

198  
189 282. A programmable infusion system in accordance with claim  
273, wherein said pump means executes in pulses, said recording  
means comprising a pulse rate detector comprising:  
P<sub>1</sub> means for counting the number of times said ~~pumping~~ means  
pumps over a preselected time period, said counting means  
storing the count;  
P<sub>2</sub> minimum rate memory means for storing a programmable number  
input corresponding to a minimum medication infusion rate; and  
P<sub>3</sub> means for comparing the number counted by said counting  
means with said programmable number input stored in said minimum  
rate memory means.

199  
188 283. A programmable infusion system in accordance with claim  
282, further comprising means for providing an alarm signal when  
said count is less than said programmable number input stored in  
said minimum rate memory means.

200  
187 284. A programmable infusion system in accordance with claim  
283, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

201  
186 285. A programmable infusion system in accordance with claim  
283, wherein said counting means comprises a pressure  
transducer.



202  
199 202  
E 112 202. A programmable infusion system in accordance with claim 202, wherein said comparing means is coupled to said telemetry means for telemetering information <sup>outputted</sup> ~~deduced~~ by said comparing means out of said living body.

203  
189 203  
273. A programmable infusion system in accordance with claim 273, wherein said pump means executes in pulses, said recording means comprising a pulse recorder comprising:

E 1 means for counting the number of times said <sup>pump</sup> ~~pumping~~ means pumps over a preselected time period, said counting means storing the count; and

E 1 means for counting the number of times said <sup>pump</sup> ~~pumping~~ means is commanded to pump over said preselected time period.

D1 204  
E 204. A programmable infusion system in accordance with claim 204, wherein said pulse recorder further comprises means for comparing the <sup>numbers</sup> ~~number~~ recorded by both said counting means.

205  
204 205  
E 112 205. A programmable infusion system in accordance with claim 205, wherein said comparing means is coupled to said telemetry means for telemetering information <sup>outputted</sup> ~~deduced~~ by said comparing means out of said living body.

206  
203 206  
207. A programmable infusion system in accordance with claim 207, further comprising means for providing an alarm signal when said numbers recorded by both said counting means are different.

207  
206 207  
208. A programmable infusion system in accordance with claim 208, wherein said alarm signal comprises a subcutaneous electrical stimulation.

208  
203  
202. A programmable infusion system in accordance with claim 201, wherein said recording means is coupled to said telemetry means for telemetering information recorded by both said counting means out of said living body.

209  
203  
202. A programmable infusion system in accordance with claim 201, wherein said first recited counting means comprises a pressure transducer.

210  
189  
202. A programmable infusion system in accordance with claim 201, wherein said recording means is powered by said implanted power source.

211  
110  
202. A programmable infusion system in accordance with claim 201 further comprising means for maintaining the pressure within said medication reservoir at a pressure level below the internal pressure of said living body.

212  
211  
202. A programmable infusion system in accordance with claim 201, wherein said pressure maintaining means comprises:  
P<sub>1</sub> a flexible diaphragm which divides said medication reservoir into a medication chamber and a liquid-vapor pool chamber; and  
P<sub>1</sub> a liquid vapor pool disposed within said liquid-vapor pool chamber, the proportion of liquid to vapor in said liquid-vapor pool varying in response to variations in the amount of said selected medication disposed in said medication chamber.

213  
212  
202. A programmable infusion system in accordance with claim 201, said infusion apparatus further comprising switch means disposed within said medication reservoir, said switch means being coupled to said telemetry means and being activated when said flexible diaphragm is disposed in a preselected relationship <sup>relative</sup> to said switch means, said telemetry means

telemetering a signal indicative of such an operational condition to said telemetry receiving means.

214  
298. A programmable infusion system in accordance with claim 213, wherein said switch means is activated by pressure exerted thereon by said flexible diaphragm, said pressure being less than the ambient pressure of said body.

215  
212 299. A programmable infusion system in accordance with claim 296, said infusion apparatus further comprising an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber, said reservoir inlet valve being operable ~~and~~ when the pressure in said antechamber exceeds the pressure in the <sup>said medication</sup> reservoir chamber by more than a predetermined differential.

216  
215 300. A programmable infusion system in accordance with claim 299, wherein the <sup>volume</sup> valve of said antechamber is less than 10% the <sup>volume medication</sup> valve of said <sup>medication</sup> reservoir chamber.

217  
215 301. A programmable infusion system in accordance with claim 299, further comprising an inlet filter means operably disposed between said antechamber and said medication chamber for preventing impurities in said selected medication in said antechamber from passing into said medication chamber when said reservoir inlet valve is opened, said filter means also preventing said selected medication in said medication chamber from rapidly entering said living body in the event of a leak in said inlet valve.

218  
110 302. A programmable infusion system in accordance with claim 299, further comprising means for programmed pumping of fixed-volume pulses of medication into said living body.

219  
110 303. A programmable infusion system in accordance with claim  
194, further comprising means for injecting medication into said  
medication reservoir, said injecting means being coupled to said  
telemetering receiver means, and programming means coupled to  
said <sup>telemetry</sup> ~~telemetering~~ means for indicating when ejection of  
medication into said medication reservoir is appropriate.

220  
110 304. A programmable infusion system in accordance with claim  
194, wherein said programming means is powered by said supply  
means.

221  
305. A programmable infusion system for providing medication  
to a living body <sup>of a patient</sup> comprising:

P<sub>1</sub> an infusion apparatus for implantation in said living body,  
said apparatus including

P<sub>2</sub> a medication reservoir for storing selected medication,  
P<sub>2</sub> means for infusing said selected medication stored in  
said medication reservoir into said living body, said infusion  
means having a fluid handling mechanism for delivering said  
selected medication and at least one remotely commandable  
operational characteristic,

P<sub>2</sub> command receiver means coupled to said infusion means  
for receiving command signals, and

P<sub>2</sub> means for telemetering operational information  
pertaining to said infusion apparatus out of said living body,  
said operational information including information about the  
operation of said fluid handling mechanism of said infusion  
means;

P<sub>1</sub> command source means external to said living body for  
transmitting said command signals to be received by said command  
receiver means; and

P means for receiving said telemetered operational information external to said living body.

<sup>222</sup>  
~~221~~ 306. A programmable infusion system in accordance with claim 305, wherein said fluid handling mechanism comprises means for pumping said selected medication.

Sub E16  
CLAIM  
222-224  
on  
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307. A programmable infusion system in accordance with claim 306, wherein ~~the~~ <sup>said pump means further comprises</sup> amount of medication pumped by said pump means ~~is controlled by a pressure limit in said pump means.~~ <sup>pressure limiting means for controlling</sup>

~~225~~ 224  
308. A programmable infusion system in accordance with claim 307, wherein said pump means operates in a pulsatile mode.

225  
309. A programmable infusion system in accordance with claim 308, wherein said pump means pumps a fixed volume of said selected medication each time said pump means is pulsed.

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K  
226  
310. A programmable infusion system in accordance with claim 309, wherein said pump means comprises variable volume means for storing said selected medication within said pump means, an increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, a decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.

Sub E17  
311. A programmable infusion system in accordance with claim 310, wherein said variable volume means comprises at least one flexible wall, movement of said <sup>at least one</sup> flexible wall varying the value of said variable volume means, and means for moving said <sup>at least one</sup> flexible wall.

312. A programmable infusion system in accordance with claim 311, further comprising spring means for urging said <sup>at least one flexible</sup> wall in a manner which decreases the volume of said variable volume means, the magnitude of the force applied to and stored by said spring means increasing as the volume of said variable volume means increases due to the displacement of said <sup>at least one</sup> flexible wall thereof by said moving means.

313. A programmable infusion system in accordance with claim 312, wherein said flexible wall comprises a bellows assembly having mounted on one end thereof a plate, the other end of said bellows being in communication with said selected medication, the walls of said bellows serving as said spring means.

224 230  
314. A programmable infusion system in accordance with claim 312, wherein said plate has a surface in contact with said selected medication when drawn into said variable volume means.

231  
315. A programmable infusion system in accordance with claim 314, wherein said bellows <sup>assembly</sup> is inhibited from moving said plate when the pressure (p) in said <sup>variable</sup> volume means exceeds the spring force (F) of said bellows <sup>assembly</sup> divided by the wetted area (A) of said surface of said plate in contact with said selected medication, that is when  $p > \frac{F}{A}$ .

CLAIMS 2/8  
232 233  
316. A programmable infusion system in accordance with claim 313, wherein ~~said moving means comprises said plate being~~ <sup>is</sup> magnetizable, and a coil disposed proximate to said plate, said coil selectively radiating a pulsing magnetic field, pulsing of said coil causing said plate to be moved.

233  
232  
317. A programmable infusion system in accordance with claim 316, wherein said plate comprises a permanent magnet.

237  
227  
318. A programmable infusion system in accordance with claim 313, further comprising means for limiting the distance said plate can move in both <sup>a</sup>the volume increasing direction and <sup>a</sup>the volume decreasing direction.

235  
226  
319. A programmable infusion system in accordance with claim 310, wherein said infusion means further comprises:

P<sub>1</sub> an interface pressure valve through which said selected medication enters said variable volume means from said medication reservoir, said interface pressure valve being normally closed;

P<sub>2</sub> an outlet chamber which is in communication with said living body; and

D1 P<sub>3</sub> an outlet pressure valve located between said variable volume means and said outlet chamber, said outlet pressure valve being normally closed, an increase in volume of said variable volume means causing said interface pressure valve to open and medication to enter said variable volume means, a decrease in volume of said variable volume means causing said outlet pressure valve to open and said interface pressure valve to close, so as to permit medication to enter said outlet chamber as a pressure pulse.

236  
235  
320. A programmable infusion system in accordance with claim 319, wherein said outlet chamber comprises an elastic wall having a fluidic capacitive effect on the flow of said selected medication and a filter element through which liquid flow to the said living body is resisted, said elastic wall and said filter comprising a fluid resistance-capacitance arrangement with respect to said flow of said selected medication from said outlet chamber into said living body.

22-237  
321. A programmable infusion system in accordance with claim 320, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.

238  
322. A programmable infusion system in accordance with claim 321, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.

239  
323. A programmable infusion system in accordance with claim 320, wherein said infusion means further comprises an outlet chamber which is in communication with said living body, said pump means expelling said selected medication into said outlet chamber means, and means for monitoring the operation of said pump means, said monitoring means being disposed in said outlet chamber and providing a signal in response to a pressure pulse in said outlet chamber caused by said pump means, said monitoring means being operably coupled to said telemetry means.

240  
324. A programmable infusion system in accordance with claim 323, wherein said monitoring means comprises a pressure transducer.

241  
325. A programmable infusion system in accordance with claim 323, further comprising first means for indicating the operation of said pump means when a decrease in volume of said variable volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.



241 326. A programmable infusion system in accordance with claim 325, further comprising second means for indicating the operation of said pump means wherein a signal is provided by said monitoring means absent a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

243 327. A programmable infusion system in accordance with claim 326, further comprising means for monitoring the operation of said pump means, said monitoring means being operably coupled to said telemetry means.

243 328. A programmable infusion system in accordance with claim 327, wherein said monitoring means comprises pressure sensing means disposed in the path of flow of said selected medication into said ~~living~~ <sup>living</sup> body, said pressure sensing means providing a signal in response to a pressure pulse in said path of flow.

D1 Sub E19

329. A programmable infusion system in accordance with claim 328, <sup>(insert body of claim 104 "wherein ... lead"), said system</sup> further comprising first means for indicating the operation of said pump means when a decrease in volume of said variable volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

245 330. A programmable infusion system in accordance with claim 329, further comprising second means for indicating the operation of said pump means <sup>when</sup> ~~wherein~~ a signal is provided by said monitoring means absent a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

247  
331. A programmable infusion system in accordance with claim 330, wherein one of said command signals transmitted by said command source means comprises a signal which corresponds to a selected operational rate at which said infusion means will infuse said selected medication into said living body.

248  
332. A programmable infusion system in accordance with claim 331, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a plurality of operational medication dose inputs each corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected <sup>one of</sup> said medication dose <sup>inputs</sup> ~~input~~.

249  
333. A programmable infusion system in accordance with claim 332, wherein said infusion apparatus further comprises electronic control means coupled to said infusion means and said command receiver means, said electronic control means <sup>including means</sup> for maintaining a history of the infusion rate at which said infusion means has operated, said electronic control means <sup>including means</sup> for precluding the infusion of said selected medication by said infusion means if said rate requested by said patient programming unit exceeds a predetermined safe medication infusion rate based on said maintained history.

250  
334. A programmable infusion system in accordance with claim 333, wherein said electronic control means is coupled to said telemetry means, said patient programming unit including means for indicating to said patient if said selected infusion rate exceeds said predetermined safe medication infusion rate, said ~~electronic~~ <sup>selective</sup> control means selectively sending a signal to said

indicating means via said telemetry means and said telemetry receiving means, said telemetry receiving means being coupled to said indicating means.

E <sup>248 251</sup>  
~~335~~ 335. A programmable infusion system in accordance with claim ~~334~~, wherein said patient programming unit further comprises annunciator means and visual display means for providing information regarding previously selected medication infusion rates, for indicating whether a proper programming of a presently requested infusion rate has been communicated to said command receiver, and for selectively providing information as to the time and rate of previously selected medication infusion.

D1 <sup>252</sup>  
~~336~~ 336. A programmable infusion system in accordance with claim ~~335~~, further comprising means for selectively supplying power to said command receiver means, said supply means being coupled to an external power source, said supply means being external to said living body, said infusion means being powered by an implanted power source.

<sup>253</sup>  
~~337~~ 337. A programmable infusion system, in accordance with Claim ~~336~~ <sup>252</sup>, wherein said supply means provides an alternating field.

<sup>254</sup>  
~~338~~ 338. A programmable infusion system, in accordance with claim ~~337~~ <sup>253</sup>, wherein said infusion apparatus further comprises detector means for detecting said alternating field and for converting the same into electrical energy, said detecting means being coupled to said command receiver.

<sup>255</sup>  
~~339~~ 339. A programmable infusion system in accordance with claim ~~338~~ <sup>254</sup>, wherein said infusion apparatus further comprises means for rectifying said electrical energy into a d.c. power signal.

<sup>254</sup>  
~~340~~. A programmable infusion system in accordance with claim ~~339~~, wherein said d.c. power signal is coupled to said implanted power source to effect the charging thereof.

<sup>257</sup>  
~~255~~<sup>341</sup>. A programmable infusion system in accordance with claim ~~339~~, wherein said telemetry means is coupled to said rectifier means and is powered by said d.c. power signal.

<sup>258</sup>  
~~252~~<sup>342</sup>. A programmable infusion system in accordance with claim ~~336~~, wherein said telemetry means is also supplied power by said supply means.

<sup>259</sup>  
~~252~~<sup>343</sup>. A programmable infusion system in accordance with claim ~~336~~, further comprising means for selectively recharging said implanted power source, said recharging means being powered by said supply means.

<sup>260</sup>  
~~252~~<sup>344</sup>. A programmable infusion system in accordance with claim ~~305~~, wherein one of said <sup>at least one</sup> remotely commandable operational characteristic~~s~~ comprises an infusion rate variable on command, said infusion apparatus further comprising means for inhibiting sad infusion apparatus further comprising means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded by a commanded infusion rate, said inhibiting means being operably coupled to said infusion means.

<sup>261</sup>  
~~260~~<sup>345</sup>. A programmable infusion system in accordance with claim ~~344~~, wherein said inhibiting means comprises at least one means for defining a fixed infusion rate limit.

<sup>262</sup>  
~~261~~<sup>346</sup>. A programmable infusion system in accordance with claim ~~345~~, wherein said <sup>at least one</sup> means for defining a fixed infusion rate limit is hardwired.

263  
260  
347. A programmable infusion system in accordance with claim 344, wherein said preselected medication infusion rate is remotely selectable.

264  
260  
348. A programmable infusion system in accordance with claim 344, wherein said preselected medication infusion rate comprises a remotely selectable rate and a fixed rate, said remotely selectable rate being limited by said fixed rate.

265-267  
349. A programmable infusion system in accordance with claim 348, wherein said inhibiting means comprises:

at least one programmable rate memory unit coupled to said command receiver means, each of said <sup>at least one</sup> programmable rate memory units for receiving and storing an infusion rate input command corresponding to said remotely selectable rate;

at least one limit control unit, each of <sup>at least one limit control unit providing</sup> which provides a fixed rate limit; and

means for comparing each of said infusion rate input commands to a corresponding said fixed rate limit, infusion of said medication at a rate exceeding said fixed rate limit being inhibited.

266 260  
265  
350. A programmable infusion system in accordance with claim 349, further comprising command decoder means for coupling said <sup>units</sup> at least one said programmable rate memory <sup>unit</sup> to said command receiver means, said command decoder means for decoding said command signals received by said command receiver means into said infusion rate inputs for receipt by and storage in <sup>corresponding</sup> said at least one programmable rate memory <sup>units</sup> <sup>units</sup>.

267  
265  
351. A programmable infusion system in accordance with claim 349, wherein each of said <sup>at least one</sup> limit control units are hardwired. ✓

<sup>264</sup>  
~~265~~ 342. A programmable infusion system in accordance with claim  
~~349~~, further comprising means for generating an alarm signal  
when any infusion rate input command exceeds a corresponding  
fixed rate limit.

<sup>269</sup>  
~~265~~ 353. A programmable infusion system in accordance with claim  
~~349~~, wherein said inhibiting means precludes infusion of said  
medication by said infusion means when the selected said  
commandable infusion rate exceeds said preselected <sup>medication</sup> infusion rate  
during a ~~fixed~~ <sup>of a predetermined length</sup> window of time which shifts continuously.

<sup>270</sup>  
~~260~~ 354. A programmable infusion system in accordance with claim  
~~344~~, wherein said inhibiting means precludes infusion of said  
medication by said infusion means when the selected said  
commandable infusion rate exceeds said preselected infusion rate ✓  
during a ~~fixed~~ window of time which shifts continuously.

*Sub E21*  
*211-273*  
*NEW*  
*N*  
*K*  
*N*  
*P*  
355. A programmable infusion system in accordance with claim  
344, wherein said fluid handling mechanism of said infusion  
means includes a pump means which executes in pulses, said  
inhibiting means comprising a programmable memory rate unit  
coupled to said command receiver for storing initially a <sup>dose limit</sup> number  
corresponding to a first maximum number of infusion pulses  
preselected as allowable <sup>E</sup> during a first shifting time window of  
a predetermined length, pulse quantities being subtracted from  
said ~~first~~ number stored in said programmable memory rate unit  
as infusion pulses are executed by said infusion means, pulse  
quantities being added to said ~~first~~ number as time elapses such  
that said number does not exceed said first maximum number, said  
subtraction and addition being accomplished in running integral  
fashion, said inhibiting means not permitting pulsing of said  
pump means <sup>at a rate</sup> a number of times in excess of <sup>the rate represented by</sup> said number stored in  
said programmable memory rate unit. <sup>dose limit</sup>

356. A programmable infusion system in accordance with claim 355, wherein said memory rate unit also records the number of pulses which have been inhibited and causes said pump means of said fluid handling mechanism to execute said pulses when said pulses can be subtracted from said <sup>dose limit</sup> number stored in said programmable memory rate unit as a result of the elapse of time.

357. A programmable infusion system in accordance with claim 355, wherein said programmable memory rate unit also stores initially another number corresponding to a second maximum number of infusion pulses preselected as allowable during a second shifting time window of a predetermined length, said second ~~fixed~~ shifting time window being longer in length than said first shifting time window, pulse quantities being subtracted from said another <sup>dose limit</sup> number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said <sup>another dose limit</sup> second number as time elapses such that said another <sup>dose limit</sup> number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means <sup>at a rate</sup> a number of times in excess of said <sup>the rate represented by</sup> another number stored in said programmable memory rate unit. <sup>dose limit</sup>

273 274 358. A programmable infusion system in accordance with claim 357, wherein said rate memory unit also records the number of pulses which have been inhibited and causes said pump means of said fluid handling mechanism to execute said pulses when said pulses can be subtracted from <sup>both</sup> said <sup>dose limit</sup> numbers stored in said programmable memory rate unit.

274 275 359. A programmable infusion system in accordance with claim 358, wherein said inhibiting means further comprises at least

one fixed infusion rate limit which limits the total maximum infusion rate of said infusion means.

275 <sup>276</sup>  
360. A programmable infusion system in accordance with claim 359, wherein said fixed infusion rate limit is hardwired.

277  
273 <sup>277</sup>  
361. A programmable infusion system in accordance with claim 357, further comprising means for generating an alarm signal when any commanded infusion rate results in the inhibiting of pulsing of said pump means by said inhibiting means.

278  
277 <sup>278</sup>  
362. A programmable infusion system in accordance with claim 361, wherein said alarm signal comprises a subcutaneous electrical stimulation.

D/ 279  
273 <sup>279</sup>  
363. A programmable infusion system in accordance with claim 357, further comprising command decoder means for coupling said command receiver means to said programmable memory rate unit, said command decoder means for decoding said command signals received by said command receiver means into said first and second <sup>maximum</sup> numbers of infusion pulses.

E 280  
F <sup>260</sup>  
364. A programmable infusion system in accordance with claim 344, wherein said inhibiting means is operably coupled to said telemetry means, said inhibiting means providing a signal to said telemetry means for telemetering to said telemetry receiving means operational information pertaining to the functions of said inhibiting means.

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265 <sup>281</sup>  
365. A programmable infusion system in accordance with claim 344, further comprising means for generating an alarm signal when said inhibiting means inhibits said infusion means.

118



282  
266. A programmable infusion system in accordance with claim 265, further comprising means for recording when said inhibiting means inhibits said infusion means.

283  
267. A programmable infusion system in accordance with claim 266, wherein said recording means is coupled to said telemetry means, said recording means providing a signal to said telemetry means for telemetering to said telemetry receiving means operational information pertaining to said inhibiting means as recorded by said recording means.

284  
268. A programmable infusion system in accordance with claim 267, said infusion apparatus further comprising means for generating a distinctive alarm signal pattern for each of a plurality of improper <sup>operational</sup> ~~operation~~ conditions.

285-297  
369. A programmable infusion system in accordance with claim 368, wherein said alarm signal <sup>is delivered</sup> ~~is delivered~~ to said living body subcutaneously. <sup>pattern</sup>

370. A programmable infusion system in accordance with claim 369, further comprising means for detecting a medication leak, coupled to said alarm means, wherein one of said improper <sup>all</sup> ~~operation~~ conditions comprises a medication leak out of said medication reservoir.

371. A programmable infusion system in accordance with claim 369, further comprising means for detecting a body fluid leak, coupled to said alarm <sup>generator</sup> ~~means~~, wherein one of said improper <sup>all</sup> ~~operation~~ conditions comprises a leak of body fluids into said infusion apparatus.

372. A programmable infusion system in accordance with claim 369, further comprising means for detecting the rate at which said infusion means is operating, <sup>said rate detecting means being</sup> coupled to said alarm <sup>generating</sup> means, wherein one of said improper operation <sup>al</sup> conditions comprises operation of said infusion means at an improper rate.

(4) 373. A programmable infusion system in accordance with claim 369, wherein one of said improper operation <sup>al</sup> conditions comprises receiving of a command by said command receiver <sup>means</sup> which cannot be executed.

(5) 374. A programmable infusion system in accordance with claim 369, further comprising <sup>a</sup> battery means for powering said infusion means and means for determining the voltage of said battery <sup>means</sup>, <sup>said voltage detecting means being</sup> coupled to said alarm <sup>generating</sup> means, wherein one of said improper operation <sup>al</sup> conditions <sup>means</sup> comprises low battery <sup>al</sup> voltage.

D1

(6) 375. A programmable infusion system in accordance with claim 369, further comprising means for detecting the amount of <sup>said medication amount detecting means being</sup> medication disposed in said reservoir <sup>al</sup> coupled to said alarm <sup>generating</sup> means, wherein one of said improper operation conditions comprises a preselected amount of medication remaining in said medication reservoir.

(7) 376. A programmable infusion system in accordance with claim 368, further comprising means for detecting a medication leak, <sup>said medication detecting means being</sup> coupled to said alarm <sup>generating</sup> means, wherein one of said improper operation <sup>al</sup> conditions comprises a medication leak out of said medication reservoir.

(8) 377. A programmable infusion system in accordance with claim 368, further comprising means for detecting a body fluid leak, <sup>said body fluid leak detecting means being</sup> coupled to said alarm <sup>generating</sup> means, wherein one of said improper

operation<sup>al</sup> conditions comprises a leak of body fluids into said infusion apparatus.

378. A programmable infusion system in accordance with claim 368, further comprising means for detecting the rate at which said infusion means is operating, <sup>said rate detecting means being</sup> coupled to said alarm means, wherein one of said improper operation<sup>al</sup> conditions comprises <sup>generating</sup> operation of said invasion means at an improper rate.

379. A programmable infusion system in accordance with claim 368, wherein one of said improper operation<sup>al</sup> conditions comprises receiving of a command by said command receiver<sup>means</sup>, which cannot be executed.

380. A programmable infusion system in accordance with claim 368, further comprising <sup>a</sup> battery means for powering said infusion means and means for determining the voltage of said battery <sup>determining means being</sup> means, <sup>coupled to said alarm means, wherein one of said improper operation<sup>al</sup> conditions, <sup>generating</sup> comprises low battery<sup>means</sup> voltage.</sup>

381. A programmable infusion system in accordance with claim 368, further comprising means for detecting the amount of medication disposed in said reservoir, <sup>said medication detecting means being</sup> coupled to said alarm means, wherein one of said improper operation<sup>al</sup> conditions <sup>generating</sup> comprises a preselected amount of medication remaining in said medication reservoir.

284 298  
382. A programmable infusion system in accordance with claim 368, further comprising means for simulating said improper operational conditions for test <sup>purposes</sup> purposes.

221 299 ✓  
383. A programmable infusion system in accordance with claim 365, wherein said fluid handling mechanism includes means for

pumping a preselected amount of medication into said living body, said infusion apparatus further comprising means for recording the rate at which pumping is effected by said pumping means.

E  
M

CLAIMS  
Sub E 23

300-301

SA.  
yellow

384. A programmable infusion system in accordance with claim 383, wherein said recording means comprises:

means for storing the rate at which said pumping means pumps over a preselected time period;

means for storing a programmable input corresponding to a minimum medication infusion rate; and

means for comparing the rate recorded by said <sup>first recited storing</sup> recording means to the rate stored in said <sup>second recited</sup> storing means.

301  
300 385. A programmable infusion system in accordance with claim

384, further comprising means for providing an alarm signal when

E D1  
input corresponding to said <sup>first recited storing is</sup> said rate recorded by said <sup>recording</sup> means if less than said <sup>programmable</sup> minimum medication infusion rate.

indicated by said second recited storing means.

302  
300 386. A programmable infusion system in accordance with claim

384, wherein said recording means is coupled to said telemetry

E  
means for telemetering information <sup>recorded by</sup> ~~received~~ by said recording means out of said living body.

303  
299 387. A programmable infusion system in accordance with claim

383, wherein said recording means comprises:

E P  
means for storing the rate at which said <sup>pump</sup> ~~pumping~~ means pumps over a preselected time period; and

E  
means for storing the rate at which said <sup>pump</sup> ~~pumping~~ means is signalled to pump over said preselected time period.

304  
313 388. A programmable infusion system in accordance with claim

384, further comprising means for comparing the rates recorded by both said storing means.

12

305  
304  
309. A programmable infusion system in accordance with claim 308, wherein said comparing means is coupled to said telemetry means for telemetering information <sup>outputted</sup> ~~deduced~~ by said comparing means out of said living body.

306  
304  
310. A programmable infusion system in accordance with claim 308, further comprising means for providing an alarm signal when the rate at which said <sup>pump</sup> ~~pumping~~ means pumps is different than the rate at which said <sup>pump</sup> ~~pumping~~ means <sup>is</sup> ~~is~~ signalled to pump.

307  
303  
311. A programmable infusion system in accordance with claim 307, wherein said recording means is coupled to said telemetry means for telemetering information recorded by ~~both~~ said recording means out of said living body.

308  
309  
312. A programmable infusion system in accordance with claim 308, wherein said pump means executes in pulses, said recording means comprising a pulse rate detector comprising:  
P means for counting the number of times said <sup>pump</sup> ~~pumping~~ means pumps over a preselected time period, said counting means storing the count;  
P minimum rate memory means for storing a programmable number input corresponding to a minimum medication infusion rate; and  
P means for comparing the number counted by said counting means with said programmable number input stored in said minimum rate memory means.

309  
308  
313. A programmable infusion system in accordance with claim 312, further comprising means for providing an alarm signal when said count is less than said programmable number input stored in said minimum rate memory means.

309 <sup>310</sup> 394. A programmable infusion system in accordance with claim 393, wherein said alarm signal comprises a subcutaneous electrical stimulation.

309 <sup>311</sup> 395. A programmable infusion system in accordance with claim 393, wherein said counting means comprises a pressure transducer.

E 308 <sup>312</sup> 396. A programmable infusion system in accordance with claim 393, wherein said comparing means is coupled to said telemetry means for telemetering information <sup>not outputted</sup> ~~deduced~~ by said comparing means out of said living body.

D1 309 <sup>313</sup> 397. A programmable infusion system in accordance with claim 393, wherein said pump means executes in pulses, said recording means comprising a pulse recorder comprising:

E 309 <sup>313</sup> 397. A programmable infusion system in accordance with claim 393, wherein said pump means executes in pulses, said recording means comprising a pulse recorder comprising:

1 means for counting the number of times said <sup>pump</sup> ~~pumping~~ means pumps over a preselected time period, said counting means storing the count; and

E 309 <sup>313</sup> 397. A programmable infusion system in accordance with claim 393, wherein said pump means executes in pulses, said recording means comprising a pulse recorder comprising:

1 means for counting the number of times said <sup>pump</sup> ~~pumping~~ means is commanded to pump over said preselected time period.

E 309 <sup>314</sup> 398. A programmable infusion system in accordance with claim 397, wherein said pulse recorder further comprises means for comparing the <sup>numbers</sup> ~~number~~ recorded by both said counting means.

E 309 <sup>315</sup> 399. A programmable infusion system in accordance with claim 398, wherein said comparing means is coupled to said telemetry means for telemetering information <sup>outputted</sup> ~~deduced~~ by said comparing means out of said living body.

127

✓ <sup>316</sup>  
~~315~~ <sup>316</sup> 400. A programmable infusion system in accordance with claim  
~~397~~, further comprising means for providing an alarm signal when  
said numbers recorded by both said counting means are different.

<sup>317</sup>  
~~316~~ <sup>317</sup> 401. A programmable infusion system in accordance with claim  
400, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

<sup>318</sup>  
- ~~315~~ <sup>318</sup> 402. A programmable infusion system in accordance with claim  
~~397~~, wherein said recording means is coupled to said telemetry  
means for telemetering information recorded by both said  
counting means out of said living body.

D1 <sup>319</sup>  
✓ ~~315~~ <sup>319</sup> 403. A programmable infusion system in accordance with claim  
~~397~~, wherein said first recited counting means comprises a  
pressure transducer.

(M) <sup>320</sup>  
~~221~~ <sup>320</sup> 404. A programmable infusion system in accordance with claim  
~~305~~, further comprising means for maintaining the pressure within  
said medication reservoir at a pressure level below the internal  
pressure of said living body.

<sup>321</sup>  
~~320~~ <sup>321</sup> 405. A programmable infusion system in accordance with claim  
~~404~~, wherein said pressure maintaining means comprises:

P. a flexible diaphragm which divides said medication reservoir  
into a medication chamber and a liquid-vapor pool chamber; and

P. a liquid vapor pool disposed within said liquid-vapor pool  
chamber, the proportion of liquid to vapor in said liquid-vapor  
pool varying in response to variations in the amount of said  
selected medication disposed in said medication chamber.

<sup>322</sup>  
~~320~~ <sup>322</sup> 406. A programmable infusion system in accordance with claim  
~~305~~, said infusion apparatus further comprising switch means

disposed within said medication reservoir, said switch means being coupled to said telemetry means and being activated when said flexible diaphragm is disposed in a preselected relationship relative to said switch means, said telemetry means telemetering a signal indicative of such an operational condition to said telemetry receiving means.

323  
322 407. A programmable infusion system in accordance with claim 406, wherein said switch means is activated by pressure exerted thereon by said flexible diaphragm, said pressure being less than the ambient pressure of said body.

324  
320 408. A programmable infusion system in accordance with claim 405, said infusion apparatus further comprising an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber, said reservoir inlet valve being operable ~~and~~ when the pressure in said antechamber exceeds the pressure in <sup>said medication</sup> ~~the reservoir~~ chamber by more than a predetermined differential.

325  
324 409. A programmable infusion system in accordance with claim 408, wherein the volume of said antechamber is less than 10% the volume of said <sup>medication</sup> ~~reservoir~~ chamber.

326  
324 410. A programmable infusion system in accordance with claim 408, further comprising an inlet filter means operably disposed between said antechamber and said medication chamber for preventing impurities in said selected medication in said ~~antechamber~~ <sup>antechamber</sup> from passing into said medication chamber when <sup>said</sup> ~~the~~ reservoir inlet valve is opened, said filter means also preventing said selected medication in said medication chamber from rapidly entering said living body in the event of a leak in said inlet valve.



327  
321  
305, 411. A programmable infusion system in accordance with claim  
further comprising means for programmed pumping of  
fixed-volume pulses of medication into said living body.

✓ 328  
412. A programmable infusion system for providing medication  
to a living body <sup>for patient</sup> comprising:

P<sub>1</sub> an infusion apparatus for implantation in said living body,  
said apparatus including

P<sub>2</sub> a medication reservoir for storing selected medication,

P<sub>2</sub> means for infusing said selected medication stored in  
said medication reservoir into said living body, said infusion  
means having an infusion rate variable upon command,

P<sub>2</sub> command receiver means coupled to said infusion means  
for receiving command signals, and

P<sub>2</sub> means for inhibiting said infusion means from infusing  
said selected medication if a preselected medication infusion  
rate is exceeded, said inhibiting means being operably coupled  
to said infusion means; and

P<sub>1</sub> command source means external to said living body for  
transmitting said command signals to be received by said command  
receiver means.

329  
328  
413. A programmable infusion system in accordance with claim  
412, wherein said inhibiting means comprises at least one means  
for defining a fixed infusion rate limit.

330  
329  
414. A programmable infusion system in accordance with claim  
413, wherein said <sup>at least one</sup> means for defining a fixed infusion rate limit  
is hardwired.

331  
330 415. A programmable infusion system in accordance with claim 412, wherein said preselected medication infusion rate is remotely selectable.

332 332  
328 416. A programmable infusion system in accordance with claim 412, wherein said preselected medication infusion rate comprises a remotely selectable rate and a fixed rate, said remotely selectable rate being limited by said fixed rate.

CLAIM 24  
333 333  
417. A programmable infusion system in accordance with claim 416, wherein said inhibiting means comprises:

at least one programmable rate memory unit coupled to said command receiver means, each of said <sup>at least one</sup> programmable rate memory units for receiving and storing an infusion rate input command corresponding to said remotely selectable rate;  
at least one limit control unit, each of <sup>said at least one limit control unit providing</sup> which provides a fixed rate limit; and

means for comparing each of said infusion rate input commands to a corresponding said fixed rate limit, infusion of said medication at a rate exceeding said fixed rate limit being inhibited.

334  
333 418. A programmable infusion system in accordance with claim 417, further comprising command decoder means for coupling <sup>each of</sup> said <sup>each of</sup> at least one ~~said~~ programmable rate memory <sup>units</sup> ~~unit~~ to said command receiver means, said command decoder means for decoding said command signals received by said command receiver means into said infusion rate inputs for receipt by <sup>corresponding</sup> and storage in said at least one programmable rate memory <sup>units</sup> ~~unit~~.

335  
333 419. A programmable infusion system in accordance with claim 417, wherein each of said limit control units <sup>at least one</sup> ~~are~~ <sup>is</sup> ~~are~~ hardwired.

336 335 336

420. A programmable infusion system in accordance with claim 417, further comprising means for generating an alarm signal when any infusion rate input command exceeds a corresponding fixed rate limit.

337 335 337

E

421. A programmable infusion system in accordance with claim 417, wherein said inhibiting means precludes infusion of said medication by said infusion means when the selected said commandable infusion rate exceeds said preselected medication infusion rate during a ~~fixed~~ <sup>of a predetermined length</sup> window of time which shifts continuously.

Sub E 25  
CLAIMS  
338-341  
41111111  
DT

422. A programmable infusion system in accordance with claim 412, wherein said inhibiting means precludes infusion of said medication by said infusion means when the selected said ~~commandable~~ <sup>medication</sup> infusion rate exceeds said preselected ~~infusion rate~~ <sup>of a predetermined length</sup> during a ~~fixed~~ window of time which shifts continuously.

N  
K  
N  
P

423. A programmable infusion system in accordance with claim 412, wherein said infusion means includes a pump means which executes in pulses, said inhibiting means comprising a programmable memory rate unit coupled to said command receiver for storing initially a <sup>base limit</sup> number corresponding to a first maximum number of infusion pulses preselected as allowable during a first shifting time window of a predetermined length, pulse quantities being subtracted from said number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said stored number as time elapses such that said number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means <sup>at a rate</sup> a number of times in excess of <sup>the rate represented by</sup> said number stored in said programmable memory rate unit.

139

424. A programmable infusion system in accordance with claim 423, wherein said memory rate unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted from said <sup>dose limit</sup> number stored in said programmable memory rate unit as a result of the elapse of time.

N  
K  
N  
PP  
425. A programmable infusion system in accordance with claim 423, wherein said programmable memory rate unit also stores initially another <sup>dose limit</sup> number corresponding to a second maximum number of infusion pulses preselected as allowable during a second shifting time window of a predetermined length, said second shifting time window being longer in length than said first shifting time window, pulse quantities being subtracted from said another <sup>dose limit</sup> number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said another <sup>dose limit</sup> stored number as time elapses such that said another <sup>dose limit</sup> number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means <sup>at a rate</sup> a number of times in excess of said <sup>the rate represented by</sup> another number stored in said programmable memory ~~rate unit~~ <sup>dose limit</sup>.

341  
342  
426. A programmable infusion system in accordance with claim 425, wherein said rate memory unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted from <sup>both said dose limit numbers</sup> said number stored in said programmable memory rate unit.  
E

343  
342  
427. A programmable infusion system in accordance with claim 426, wherein said inhibiting means further comprises at least

one fixed infusion rate limit which limits the total maximum infusion rate of said infusion means.

343 <sup>344</sup>  
~~426~~. A programmable infusion system in accordance with claim 427, wherein said fixed infusion rate limit is hardwired.

341 <sup>345</sup>  
~~425~~. A programmable infusion system in accordance with claim 425, further comprising means for generating an alarm signal when any commanded infusion rate results in the inhibiting of pulsing of said pump means by said inhibiting means.

345 <sup>346</sup>  
~~429~~. A programmable infusion system in accordance with claim 429, wherein said alarm signal comprises a subcutaneous electrical stimulation.

341 <sup>347</sup>  
~~425~~. A programmable infusion system in accordance with claim 425, further comprising command decoder means for coupling said command receiver means to said programmable memory rate unit, said command decoder means for decoding said command signals received by said command receiver means into said first and <sup>maximum</sup> second numbers of infusion pulses.

D1  
E  
328 <sup>348</sup>  
~~412~~. A programmable infusion system in accordance with claim 412, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, said operational information including information pertaining to the functions of said inhibiting means, and means for receiving said telemetered operational information external to said living body.

328 <sup>349</sup>  
~~432~~. A programmable infusion system in accordance with claim 432, wherein one of said command signals transmitted by said command source means comprises a signal which corresponds to a

selected operational rate at which said infusion means will  
infuse said selected medication into said living body.

350  
328 434. A programmable infusion system in accordance with claim  
412, further comprising means for telemetering operational  
information pertaining to said infusion apparatus out of said  
living body, and means for receiving said telemetered  
operational information external to said living body, wherein  
said command source and said telemetry receiving means are  
embodied in a patient programming unit external to said living  
body, said patient programming unit having a plurality of  
operational medication dose inputs each corresponding to a  
medication infusion rate selectable and requestable by the  
patient, said patient programming unit for selectively  
transmitting a command signal corresponding to a selected <sup>one of</sup> said  
medication dose <sup>inputs</sup> ~~input~~.

351  
D1 350 435. A programmable infusion system in accordance with claim  
434, wherein said infusion apparatus further comprises  
electronic control means coupled to said infusion means and said  
command receiver means, said <sup>electronic</sup> ~~electric~~ control means <sup>including means</sup> for  
maintaining a history of the infusion rate at which said  
infusion means has operated, said <sup>including means</sup> ~~electronic~~ control means <sup>including means</sup> for  
precluding the infusion of said selected medication by said  
infusion means if said rate requested by said patient  
programming unit exceeds a predetermined safe medication  
infusion rate based on said maintained history.

352  
351 436. A programmable infusion system in accordance with claim  
435, wherein said electronic control means is coupled to said  
telemetry means, said patient programming unit including means  
for indicating to said patient if said selected infusion rate  
exceeds said predetermined safe medication infusion rate, said

8 <sup>electronic</sup>  
~~selective~~ control means selectively sending a signal to said  
indicating means via said telemetry means and said telemetry  
receiving means, said telemetry receiving means being coupled to  
said indicating means.

✓ <sup>353</sup>  
✓ <sup>331</sup> ~~435~~ 337. A programmable infusion system in accordance with claim  
~~435~~, wherein said patient programming unit further comprises  
annunciator means and visual display means for providing  
information regarding previously selected medication infusion  
rates, for indicating whether a proper programming of a  
presently requested infusion rate has been communicated to said  
command receiver, and for selectively providing information as  
to the time and rate of previously selected medication infusion.

D' <sup>354</sup>  
<sup>328</sup> ~~442~~ 438. A programmable infusion system in accordance with claim  
~~442~~, further comprising means for selectively supplying power to  
said command receiver means, said supply means being coupled to  
an external power source, said supply means being external to  
said living body, said infusion means being powered by an  
implanted power source.

<sup>355</sup>  
~~439~~ <sup>344</sup> 439. A programmable infusion system, in accordance with  
claim ~~438~~, wherein said supply means provides an alternating  
field.

<sup>356</sup>  
~~440~~ <sup>355</sup> 440. A programmable infusion system, in accordance with  
claim ~~439~~, wherein said infusion apparatus further comprises  
detector means for detecting said alternating field and for  
converting the same into electrical energy, said detecting means  
being coupled to said command receiver.

<sup>357</sup>  
<sup>356</sup> ~~440~~ 441. A programmable infusion system in accordance with claim  
~~440~~, wherein said infusion apparatus further comprises means for  
rectifying said electrical energy into a d.c. power signal.

140

<sup>358</sup>  
~~442~~. A programmable infusion system in accordance with  
<sup>357</sup>  
claim ~~441~~, wherein said d.c. power signal is coupled to said  
implanted power source to effect the charging thereof.

<sup>359</sup>  
<sup>357</sup>~~443~~. A programmable infusion system in accordance with claim  
~~441~~, further comprising means for telemetering operational  
information pertaining to said infusion apparatus out of said  
living body, and means for receiving said telemetered  
operational information external to said living body, said  
telemetry means being coupled to said rectifier means and being  
powered by said d.c. power signal.

<sup>360</sup>  
<sup>354</sup>~~444~~. A programmable infusion system in accordance with claim  
~~438~~, further comprising means for telemetering operational  
information pertaining to said infusion apparatus out of said  
living body, and means for receiving said telemetered  
operational information external to said living body, said  
telemetry means also being supplied power by said supply means.

<sup>361</sup>  
<sup>354</sup>~~445~~. A programmable infusion system in accordance with claim  
~~438~~, further comprising means for selectively recharging said  
implanted power source, said recharging means being powered by  
said supply means.

<sup>362</sup>  
<sup>328</sup>~~446~~. A programmable infusion system in accordance with claim  
~~412~~, wherein said infusion means comprises a fluid handling  
mechanism for delivering said selected medication, said  
operational information including information about the  
operation of said fluid handling mechanism.

✓ <sup>363</sup>  
<sup>362</sup>~~447~~. A programmable infusion system in accordance with claim  
~~446~~, wherein said fluid handling mechanism comprises means for  
pumping said selected medication.

DNH  
204 in  
yellow

141



NK  
NP  
Sub E 26

448. A programmable infusion system in accordance with claim 447, wherein <sup>said pump means further comprises pressure limiting means for controlling</sup> the amount of medication pumped by said pump means ~~is controlled by a pressure limit in said pump means.~~

365  
364  
449

449. A programmable infusion system in accordance with claim 447, wherein said pump means operates in a pulsatile mode.

365  
364  
450

450. A programmable infusion system in accordance with claim 449, wherein said pump means pumps a fixed volume of said selected medication each time said pump means is pulsed.

✓  
367  
364  
451

451. A programmable infusion system in accordance with claim 447, wherein said pump means comprises variable volume means for storing said selected medication within said pump means, an increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.

Sub E 27  
CLAIMS  
365-368  
364  
452

452. A programmable infusion system in accordance with claim 451, wherein said variable volume means comprises at least one flexible wall, movement of said <sup>at least one</sup> flexible wall varying the volume of said variable volume means, and means for moving said <sup>at least one</sup> flexible wall.

N  
K  
N  
P

453. A programmable infusion system in accordance with claim 452, further comprising spring means for urging said <sup>at least one flexible</sup> wall in a manner which decreases the volume of said variable volume means, the magnitude of the force applied to and stored by said spring means increasing as the volume of said variable volume means increases due to the displacement of said <sup>at least one</sup> flexible wall thereof by said moving means.

143

370  
E 369 454. A programmable infusion system in accordance with claim  
453, wherein said <sup>at least one</sup> flexible wall comprises a bellows assembly  
having mounted on one end thereof a plate, the other end of said  
bellows <sup>assembly</sup> being in communication with said selected medication,  
E the walls of said bellows <sup>assembly</sup> serving as said spring means.

371  
370 455. A programmable infusion system in accordance with claim  
454, wherein said plate has a surface in contact with said  
selected medication when drawn into said variable volume means.

372  
E 371 456. A programmable infusion system in accordance with claim  
455, wherein said bellows <sup>assembly</sup> is inhibited from moving said plate  
when the pressure (p) in said variable volume means exceeds the  
E spring force (F) of said bellows <sup>assembly</sup> divided by the wetted area (A)  
of said surface of said plate in contact with said selected  
medication, that is when  $p > \frac{F}{A}$ .

22  
D1 373  
E 370 457. A programmable infusion system in accordance with claim  
454, wherein said <sup>said plate is magnetizable,</sup> moving means ~~comprises said plate being~~  
E <sup>comprising</sup> ~~magnetizable, and~~ a coil disposed proximate to said plate, said  
coil selectively radiating a pulsing magnetic field, pulsing of  
said coil causing said plate to be moved.

374  
373 458. A programmable infusion system in accordance with claim  
457, wherein said plate comprises a permanent magnet.

375  
E 370 459. A programmable infusion system in accordance with claim  
454, further comprising means for limiting the distance said  
plate can move in both <sup>a</sup> ~~the~~ <sup>a</sup> volume increasing direction and <sup>a</sup> ~~the~~ <sup>a</sup>  
volume decreasing direction.

376  
367 460. A programmable infusion system in accordance with claim  
451, wherein said infusion means further comprises:

E <sup>valve</sup>  
 P an interface pressure ~~valve~~ through which said selected medication enters said variable volume means from said medication reservoir, said interface pressure <sup>valve</sup> ~~valve~~ being normally closed;  
 P an outlet chamber which is in communication with said living body; and  
 P an outlet pressure valve located between said variable volume means and said outlet chamber, said outlet pressure valve being normally closed, an increase in volume of said variable volume means causing said interface pressure valve to open and medication to enter said variable volume means, a decrease in volume of said variable volume means causing said outlet pressure valve to open and said interface pressure valve to close, so as to permit medication to enter said outlet chamber as a pressure pulse.

D1 377  
 376 401. A programmable infusion system in accordance with claim 360, wherein said outlet chamber comprises an elastic wall having a fluidic capacitive effect on the flow of said selected medication and a filter element through which liquid flow to the said <sup>living</sup> ~~living~~ body is resisted, said elastic wall and said filter comprising a fluid resistance - capacitance arrangement with respect to said flow of said selected medication from said outlet chamber into said living body.

E 366 378  
 460 461 462. A programmable infusion system in accordance with claim 360, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.

379  
 378 463. A programmable infusion system in accordance with claim 462, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit

146

resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.

367 <sup>380</sup>  
~~451~~. A programmable infusion system in accordance with claim  
~~451~~, further comprising means for telemetering operational  
information pertaining to said infusion apparatus out of said  
living body, and means for receiving said telemetered  
operational information external to said living body, wherein  
said infusion means further comprises an outlet chamber which is  
in communication with said living body, said pump means  
expelling said selected medication into said outlet <sup>chamber</sup> means; and  
means for monitoring the operation of said pump means, said  
monitoring means being disposed in said outlet chamber and  
providing a signal in response to a pressure pulse in said  
outlet chamber caused by said pump means, said monitoring means  
being operably coupled to said telemetry means.

D1  
381  
~~360~~ <sup>381</sup>  
~~464~~. A programmable infusion system in accordance with claim  
~~464~~, wherein said monitoring means comprises a pressure  
transducer.

382  
~~380~~ <sup>382</sup>  
~~464~~. A programmable infusion system in accordance with claim  
~~464~~, further comprising first means for indicating the operation  
of said pump means when a decrease in volume of said variable  
volume means is not followed by a signal from said monitoring  
means corresponding to a pressure pulse of said selected  
medication expelled into said outlet chamber, said first  
indicating means being operably coupled to said telemetry means.

383  
~~382~~ <sup>383</sup>  
~~464~~. A programmable infusion system in accordance with claim  
~~464~~, further comprising second means for indicating the operation  
of said pump means when a signal is provided by said monitoring  
means absent a decrease in volume of said variable volume means

E ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

363 384  
468. A programmable infusion system in accordance with claim 447, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, means for receiving said telemetered operational information external to said living body, and means for monitoring the operation of said pump means, said monitoring means being operably coupled to said telemetry means.

385  
364 469. A programmable infusion system in accordance with claim 468, wherein said monitoring means comprises pressure sensing means disposed in the path of flow of said selected medication into said living body, said pressure sensing means providing a signal in response to a pressure pulse in said path of flow.

CLAIMS Sub E 28  
386 387 470. A programmable infusion system in accordance with claim 469, further comprising first means for indicating the operation of said pump means when a decrease in volume of said variable volume means is not followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

N  
K  
N  
P  
E  
387  
386 471. A programmable infusion system in accordance with claim 470, further comprising second means for indicating the operation of said pump means when a signal is provided by said monitoring means absent a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

✓ 324 388  
412. A programmable infusion system in accordance with claim  
412, said infusion apparatus further comprising means for  
generating a distinctive alarm signal pattern for each of a  
plurality of improper <sup>operational</sup> operation conditions.

COMB E 29  
384-398  
yellow  
472. A programmable infusion system in accordance with claim  
472, wherein said alarm signal <sup>is delivered</sup> ~~is delivered~~ to said living body  
subcutaneously. <sup>pattern</sup>

474. A programmable infusion system in accordance with claim  
473, further comprising means for detecting a medication leak,  
coupled to said alarm means, wherein one of said improper  
operation <sup>generating</sup> conditions comprises a medication leak out of said  
medication reservoir.

475. A programmable infusion system in accordance with claim  
473, further comprising means for detecting a body fluid leak,  
coupled to said alarm means, wherein one of said improper  
operation <sup>generating</sup> conditions comprises a leak of body fluids into said  
infusion apparatus.

476. A programmable infusion system in accordance with claim  
473, further comprising means for detecting the rate at which  
said infusion means is operating, <sup>said rate detecting means being</sup> coupled to said alarm means,  
wherein one of said improper operation <sup>generating</sup> conditions comprises  
operation of said infusion means at an improper rate.

477. A programmable infusion system in accordance with claim  
473, wherein one of said improper operation <sup>receiving</sup> conditions comprises  
receiving of a command by said command receiver <sup>which cannot be</sup>  
executed.

478. A programmable infusion system in accordance with claim 473, further comprising <sup>or</sup> battery means for powering said infusion means and means for determining the voltage of said battery <sup>means</sup>, <sup>said voltage determination means being</sup> coupled to said alarm means, wherein one of said improper operation <sup>at</sup> conditions <sup>generating</sup> comprises low battery <sup>means</sup> voltage.

479. A programmable infusion system in accordance with claim 473, further comprising means for detecting the <sup>amount of</sup> medication disposed in said reservoir, <sup>said medication amount detecting means being</sup> coupled to said alarm means, wherein one of said improper operation <sup>at</sup> conditions <sup>generating</sup> comprises a preselected amount of medication remaining in said medication reservoir.

480. A programmable infusion system in accordance with claim 472, further comprising means for detecting a medication leak, <sup>said medication detecting means being</sup> coupled to said alarm means, wherein one of said improper operation <sup>at</sup> conditions <sup>generating</sup> comprises a medication leak out of said medication reservoir.

481. A programmable infusion system in accordance with claim 472, further comprising means for detecting a body fluid leak, <sup>said body fluid detecting means being</sup> coupled to said alarm means, wherein one of said improper operation <sup>at</sup> conditions <sup>generating</sup> comprises a leak of body fluids into said infusion apparatus.

482. A programmable infusion system in accordance with claim 472, further comprising means for detecting the rate at which said infusion means is operating, <sup>said rate detecting means being</sup> coupled to said alarm means, wherein one of said improper operation <sup>at</sup> conditions <sup>generating</sup> comprises operation of said infusion means at an improper rate.

389 483. A programmable infusion system in accordance with claim 472, wherein one of said improper <sup>operational</sup> operation <sup>at</sup> conditions comprises

ε receiving of a command by said command receiver <sup>means</sup> which cannot be executed.

Sub E 30  
CLAIMS  
400-405  
484. A programmable infusion system in accordance with claim 472, further comprising <sup>a</sup> battery means for powering said infusion means and means for determining the voltage of said battery <sup>means</sup>, <sup>said voltage determining means being</sup> coupled to said alarm means, wherein one of said improper operation <sup>generating</sup> condition <sup>means</sup> comprises low battery <sup>means</sup> voltage.

485. A programmable infusion system in accordance with claim 472, further comprising means for detecting the amount of <sup>said medication amount detecting means being</sup> medication disposed in said reservoir <sup>a</sup> coupled to said alarm means, wherein one of said improper operation <sup>generating</sup> conditions comprises a preselected amount of medication remaining in said medication reservoir.

K 388 402  
486. A programmable infusion system in accordance with claim 472, further comprising means for simulating said improper operational conditions for test purposes.

N 329 403  
487. A programmable infusion system in accordance with claim 472, wherein said infusion means includes means for pumping a preselected amount of medication into said living body, said infusion apparatus further comprising means for recording the rate at which <sup>generating</sup> pumping is effected by said pumping means.

Sub E 31  
488. A programmable infusion system in accordance with claim 487, wherein said recording means comprises:  
means for storing the rate at which said pumping means pumps over a preselected time period;  
means for storing a programmable input corresponding to a minimum medication infusion rate; and



means for comparing the rate recorded by said <sup>first recited</sup> recording means to the rate stored in said <sup>second recited</sup> storing means.

489. A programmable infusion system in accordance with claim 488, further comprising means for providing an alarm signal when said rate recorded by said <sup>first recited</sup> recording means is less than said <sup>input corresponding to said</sup> programmable minimum medication infusion rate. <sup>recorded by said second recited storing means.</sup>

406 ~~489~~. A programmable infusion system in accordance with claim ~~488~~, further comprising means for telemetering information <sup>recorded</sup> deduced by said recording means out of said living body, said telemetry means being coupled to said recording means, and means for receiving said telemetered information external to said living body.

407 ~~491~~. A programmable infusion system in accordance with claim ~~487~~, wherein said recording means comprises:

<sup>D/E</sup> ~~P~~<sub>1</sub> means for storing the rate at which said <sup>pump</sup> ~~pumping~~ means pumps over a preselected time period; and

<sup>E</sup> ~~P~~<sub>1</sub> means for storing the rate at which said <sup>pump</sup> ~~pumping~~ means is signalled to pump over said preselected time period.

408 ~~492~~. A programmable infusion system in accordance with claim ~~491~~, further comprising means for comparing the rates recorded by both said storing means.

409 ~~493~~. A programmable infusion system in accordance with claim ~~492~~, further comprising means for telemetering information <sup>outputted</sup> ~~deduced~~ by said comparing means out of said living body, said comparing means being coupled to said telemetry means, and means for receiving said telemetered information external to said living body.

408 <sup>410</sup> 494. A programmable infusion system in accordance with claim  
492, further comprising means for providing an alarm signal when  
the rate at which said <sup>pump</sup> ~~pumping~~ means pumps is different than the  
rate at which said <sup>pump</sup> ~~pumping~~ means <sup>is</sup> ~~is~~ signalled to pump.

407 <sup>411</sup> 495. A programmable infusion system in accordance with claim  
491, further comprising means for telemetering information  
recorded by ~~both~~ said recording means out of said living body,  
~~both~~ said recording means being coupled to said telemetry means,  
and means for receiving said telemetered information external to  
said living body.

403 <sup>412</sup> 496. A programmable infusion system in accordance with claim  
487, wherein said pump means executes in pulses, said recording  
means comprising a pulse rate detector comprising:  
P<sub>1</sub> means for counting the number of times said <sup>pump</sup> ~~pumping~~ means  
pumps over a preselected time period, said counting means  
storing the count;

P<sub>2</sub> minimum rate memory means for storing a programmable number  
input corresponding to a minimum medication infusion rate; and  
P<sub>3</sub> means for comparing the number counted by said counting  
means with said programmable number input stored in said minimum  
rate memory means.

412 <sup>413</sup> 497. A programmable infusion system in accordance with claim  
496, further comprising means for providing an alarm signal when  
said count is less than said programmable number input stored in  
said minimum rate memory means.

413 <sup>414</sup> 498. A programmable infusion system in accordance with claim  
497, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

160

416  
413 499. A programmable infusion system in accordance with claim 497, wherein said counting means comprises a pressure transducer.

E 416  
413 500. A programmable infusion system in accordance with claim 497, further comprising means for telemetering information ~~deduced~~ <sup>outputted</sup> by said comparing means out of said living body, said comparing means being coupled to said telemetry means, and means for receiving said telemetered operational information external to said living body.

417  
413 501. A programmable infusion system in accordance with claim 497, wherein said pump means executes in pulses, said recording means comprising a pulse recorder comprising:

E P  
D1 means for counting the number of times said ~~pump~~ <sup>pump</sup> means pumps over a preselected time period, said counting means storing the count; and

E P means for counting the number of times said ~~pump~~ <sup>pump</sup> means is commanded to pump over said preselected time period.

418  
417 502. A programmable infusion system in accordance with claim 501, wherein said pulse recorder further comprises means for comparing the ~~number~~ <sup>numbers</sup> recorded by both said counting means.

419  
418 503. A programmable infusion system in accordance with claim 502, further comprising means for telemetering information ~~deduced~~ <sup>outputted</sup> by said comparing means out of said living body, said comparing means being coupled to said telemetry means, and means for receiving said telemetered information external to said living body.

161

420  
504. A programmable infusion system in accordance with claim  
417  
501, further comprising means for providing an alarm signal when  
said numbers recorded by both said counting means are different.

421  
420 505. A programmable infusion system in accordance with claim  
504, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

422  
417 506. A programmable infusion system in accordance with claim  
501, further comprising means for telemetering information  
recorded by both said counting means out of said living body,  
said recording means being coupled to said telemetry means, and  
means for receiving said telemetered information external to  
said living body.

423  
D1 417 507. A programmable infusion system in accordance with claim  
501, wherein said first recited counting means comprises a  
pressure transducer.

424  
324 508. A programmable infusion system in accordance with claim  
417, further comprising means for maintaining the pressure  
within said medication reservoir at a pressure level below the  
internal pressure of said living body.

425  
424 509. A programmable infusion system in accordance with claim  
508, wherein said pressure maintaining means comprises:  
P<sub>1</sub> a flexible diaphragm which divides said medication reservoir  
into a medication chamber and a liquid-vapor pool chamber; and  
P<sub>2</sub> a liquid vapor pool disposed within said liquid-vapor pool  
chamber, the proportion of liquid to vapor in said liquid-vapor  
pool varying in response to variations in the amount of said  
selected medication disposed in said medication chamber.

425-426  
510

A programmable infusion system in accordance with claim 509, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, said infusion apparatus further comprising switch means disposed within said medication reservoir, said switch means being coupled to said telemetry means and being activated when said flexible diaphragm is disposed in a preselected relationship relative to said switch means, said telemetry means telemetering a signal indicative of such an operational condition to said telemetry receiving means.

427

426-511. A programmable infusion system in accordance with claim 510 wherein said switch means is activated by pressure exerted thereon by said flexible diaphragm, said pressure being less than the ambient pressure of said body.

D1

428

425-512. A programmable infusion system in accordance with claim 509, said infusion apparatus further comprising an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber, said reservoir inlet valve being operable ~~and~~ when the pressure in said antechamber exceeds the pressure in <sup>said medication</sup> ~~the reservoir~~ chamber by more than a predetermined differential.

E  
E

429

428-513. A programmable infusion system in accordance with claim 512, wherein the volume of said antechamber is less than 10% the volume of said <sup>medication</sup> ~~reservoir~~ chamber.

E

430

426-514. A programmable infusion system in accordance with claim 512, further comprising an inlet filter means operably disposed

163

between said antechamber and said medication chamber for preventing impurities in said selected medication in said antechamber from passing into said medication chamber when said reservoir inlet valve is opened, said filter means also preventing said selected medication in said medication chamber from rapidly entering said living body in the event of a leak in said inlet valve.

✓ 431  
430<sup>515</sup>. A programmable infusion system in accordance with claim 412, further comprising means for programmed pumping of fixed-volume pulses of medication into said living body.

✓ 432  
430<sup>516</sup>. A programmable infusion system in accordance with claim 412, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, means for receiving said telemetered operational information external to said living body, and means for injecting medication into said medication reservoir, said injecting means being coupled to said telemetry receiver means, and programming means coupled to said telemetry means for indicating when injection of medication into said medication reservoir is appropriate.

ε ✓ 433  
430<sup>517</sup>. A programmable infusion system for providing medication to a living body <sup>of a patient</sup> comprising:

P<sub>1</sub> An infusion apparatus for implantation in said living body, said apparatus including  
P<sub>2</sub> a medication reservoir for storing selected medication,  
P<sub>2</sub> means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having at least one remotely commandable operational characteristic.

*P* command receiver means coupled to said infusion means for receiving command signals, and

*E* *P* means for generating a distinctive alarm signal pattern for each of a plurality of improper <sup>operational</sup> ~~operation~~ conditions in said system; and

*P* command source means external to said living body for transmitting said command signals to be received by said command receiver means.

*Sub E 32*  
*CAIMS*  
*134-416*  
*on*  
*10/1/94*  
518. A programmable infusion system in accordance with claim 517, <sup>further comprising means for delivering</sup> wherein said alarm signal is <sup>Pattern</sup> delivered to said living body subcutaneously.

*D*  
*1*  
*SA*  
519. A programmable infusion system in accordance with claim 518, further comprising means for detecting a medication leak, <sup>medication detecting means being</sup> coupled to said alarm means, wherein one of said improper operation <sup>generating</sup> ~~al~~ conditions comprises a medication leak out of said medication reservoir.

*E*  
*SAID BODY*  
520. A programmable infusion system in accordance with claim 518, further comprising means for detecting a body fluid leak, <sup>fluid detecting means being</sup> coupled to said alarm means, wherein one of said improper operation <sup>generating</sup> ~~al~~ conditions comprises a leak of body fluids into said infusion apparatus.

*P*  
521. A programmable infusion system in accordance with claim 518, further comprising means for detecting the rate at which said infusion means is operating, <sup>said rate detecting means being</sup> coupled to said alarm means, wherein one of said improper operation <sup>generating</sup> ~~al~~ conditions comprises operation of said infusion means at an improper rate.

522. A programmable infusion system in accordance with claim 518, wherein one of said improper operation<sup>al</sup> conditions comprises receiving of a command by said command receiver<sup>means</sup> which cannot be executed.

523. A programmable infusion system in accordance with claim 518, further comprising<sup>a</sup> battery means for powering said infusion means and means for determining the voltage of said battery<sup>means</sup>,<sup>said voltage determining means being</sup> coupled to said alarm means, wherein one of said improper operation<sup>al</sup> conditions<sup>generating</sup> comprises low battery<sup>means</sup> voltage.

524. A programmable infusion system in accordance with claim 518, further comprising means for detecting the amount of medication disposed in said reservoir<sup>said medication amount detecting means being</sup> coupled to said alarm<sup>generating</sup> means, wherein one of said improper operation<sup>al</sup> conditions comprises a preselected amount of medication remaining in said medication reservoir.

525. A programmable infusion system in accordance with claim 517, further comprising means for detecting a medication leak, <sup>said medication</sup> coupled to said alarm<sup>means</sup>, wherein one of said improper operation<sup>al</sup> conditions<sup>generating</sup> comprises a medication leak out of said medication reservoir.

526. A programmable infusion system in accordance with claim 517, further comprising means for detecting a body fluid leak, <sup>said body</sup> coupled to said alarm means, wherein one of said improper operation<sup>al</sup> conditions<sup>generating</sup> comprises a leak of body fluids into said infusion apparatus.

527. A programmable infusion system in accordance with claim 517, further comprising means for detecting the rate at which said infusion means is operating, <sup>said rate detecting means being</sup> coupled to said alarm means,



wherein one of said improper operation<sup>al</sup> conditions comprises operation of said infusion means at an improper rate.

528. A programmable infusion system in accordance with claim 517, wherein one of said improper operation<sup>al</sup> conditions comprises receiving of a command by said command receiver<sup>means</sup> which cannot be executed.

529. A programmable infusion system in accordance with claim 517, further comprising<sup>a</sup> battery means for powering said infusion means and means for determining the voltage of said battery means, coupled to said alarm means, wherein one of said improper operation<sup>al</sup> conditions<sup>generating</sup> comprises low battery<sup>means</sup> voltage.

530. A programmable infusion system in accordance with claim 517, further comprising means for detecting the amount of medication disposed in said reservoir<sup>said medication detecting means being</sup>, coupled to said alarm means, wherein one of said improper operation<sup>al</sup> conditions<sup>generating</sup> comprises a preselected amount of medication remaining in said ~~medication reservoir.~~

447  
433  
531. A programmable infusion system in accordance with claim 517, further comprising means for simulating said improper operational conditions for test purposes.

448  
433  
532. A programmable infusion system in accordance with claim 517, wherein one of said command signals transmitted by said command source means comprises a signal which corresponds to a selected operational rate at which said infusion means will infuse said selected medication into said living body.

449  
433  
533. A programmable infusion system in accordance with claim 517, further comprising means for telemetering operational

information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, wherein said command source and said telemetry receiving means are embodied in a patient programming unit external to said living body, said patient programming unit having a plurality of operational medication dose inputs each corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected <sup>one of</sup> said medication dose <sup>inputs</sup> ~~input~~.

450  
449 534. A programmable infusion system in accordance with claim 533, wherein said infusion apparatus further comprises electronic control means coupled to said infusion means and said command receiver means, said <sup>electronic</sup> ~~electric~~ control means <sup>including means</sup> for maintaining a history of the infusion rate at which said infusion means has operated, said <sup>including means</sup> ~~electronic~~ control means for precluding the infusion of said selected medication by said infusion means if said rate requested by said patient programming unit exceeds a predetermined safe medication infusion rate based on said maintained history.

451  
450 535. A programmable infusion system in accordance with claim 534, wherein said electronic control means is coupled to said telemetry means, said patient programming unit including means for indicating to said patient if said selected infusion rate exceeds said predetermined safe medication infusion rate, said <sup>electronic</sup> ~~selective~~ control means selectively sending a signal to said indicating means via said telemetry means and said telemetry receiving means, said telemetry receiving means being coupled to said indicating means.

452  
450 536. A programmable infusion system in accordance with claim  
534, wherein said patient programming unit further comprises  
annunciator means and visual display means for providing  
information regarding previously selected medication infusion  
rates, for indicating whether a proper programming of a  
presently requested infusion rate has been communicated to said  
command receiver, and for selectively providing information as  
to the time and rate of previously selected medication infusion.

✓ 433 453  
537. A programmable infusion system in accordance with claim  
517, further comprising means for selectively supplying power to  
said command receiver means, said supply means being coupled to  
an external power source, said supply means being external to  
said living body, said infusion means being powered by an  
implanted power source.

D1 454  
538. A programmable infusion system, in accordance with  
claim 537, wherein said supply means provides an alternating  
field.

455  
539. A programmable infusion system, in accordance with  
claim 538, wherein said infusion apparatus further comprises  
detector means for detecting said alternating field and for  
converting the same into electrical energy, said detecting means  
being coupled to said command receiver.

456  
455 540. A programmable infusion system in accordance with claim  
539, wherein said infusion apparatus further comprises means for  
rectifying said electrical energy into a d.c. power signal.

457  
541. A programmable infusion system in accordance with  
claim 540, wherein said d.c. power signal is coupled to said  
implanted power source to effect the charging thereof.

171

458  
456 542. A programmable infusion system in accordance with claim  
540, further comprising means for telemetering operational  
information pertaining to said infusion apparatus out of said  
living body, and means for receiving said telemetered  
operational information external to said living body, said  
telemetry means being coupled to said rectifier means and being  
powered by said d.c. power signal.

459  
453 543. A programmable infusion system in accordance with  
claim 537, further comprising means for telemetering operational  
information pertaining to said infusion apparatus out of said  
living body, and means for receiving said telemetered  
operational information external to said living body, said  
telemetry means also being supplied power by said supply means.

D1 460  
455 544. A programmable infusion system in accordance with claim  
537, further comprising means for selectively recharging said  
implanted power source, said recharging means being powered by  
said supply means.

461  
433 545. A programmable infusion system in accordance with claim  
537, wherein said infusion means comprises a fluid handling  
mechanism for delivering said selected medication, said  
operational information including information about the  
operation of said fluid handling mechanism.

462  
461 546. A programmable infusion system in accordance with claim  
545, wherein said fluid handling mechanism comprises means for  
pumping said selected medication.

CLAIM 547  
163 on 547. A programmable infusion system in accordance with claim  
546, wherein the amount of medication pumped by said pumping  
means is controlled by a pressure limit in said pump means.  
KNOW NK  
NP

172

✓ 464  
463 548. A programmable infusion system in accordance with claim  
546, wherein said pump means operates in a pulsatile mode.

✓ 465  
464 549. A programmable infusion system in accordance with claim  
548, wherein said pump means pumps a fixed volume of said  
selected medication each time said pump means is pulsed.

✓ 466  
463 550. A programmable infusion system in accordance with claim  
546, wherein said pump means comprises variable volume means for  
storing said selected medication within said pump means, an  
increase in volume of said variable volume means permitting  
drawing of said selected medication into said pump means, <sup>a</sup>  
decrease in volume of said variable volume means permitting  
expulsion of said selected medication from said pump means.

CLAIMS  
467-472 on

✓ 467  
466 551. A programmable infusion system in accordance with claim  
550, wherein said variable volume means comprises at least one  
flexible wall, movement of said <sup>at least one</sup> flexible wall varying the volume  
of said variable volume means, and means for moving said <sup>at least one</sup>  
flexible wall.

✓ 468  
467 552. A programmable infusion system in accordance with claim  
551, further comprising spring means for urging said <sup>at least one flexible</sup> wall in a  
manner which decreases the volume of said variable volume means,  
the magnitude of the force applied to and stored by said spring  
means increasing as the volume of said variable volume means  
increases due to the displacement of said <sup>at least one</sup> flexible wall thereof  
by said moving means.

✓ 469  
468 553. A programmable infusion system in accordance with claim  
552, wherein said <sup>at least one</sup> flexible wall comprises a bellows assembly  
having mounted on one end thereof a plate, the other end of said  
bellows <sup>assembly</sup> being in communication with said selected medication,  
the walls of said bellows <sup>assembly</sup> serving as said spring means.

470  
466  
✓ 553. A programmable infusion system in accordance with claim 554, wherein said plate has a surface in contact with said selected medication when drawn into said variable volume means.

471  
555. A programmable infusion system in accordance with claim 470, wherein said bellows <sup>assembly</sup> is inhibited from moving said plate when the pressure (p) in said variable volume means exceeds the spring force (F) of said bellows <sup>assembly</sup> divided by the wetted area (A) of said surface of said plate in contact with said selected medication, that is when  $p > \frac{F}{A}$ .

535  
556. A programmable infusion system in accordance with claim 553, wherein said ~~moving means comprises~~ said plate <sup>is</sup> being magnetizable, ~~and~~ <sup>said moving means comprising</sup> a coil disposed proximate to said plate, said coil selectively radiating a pulsing magnetic field, pulsing of said coil causing said plate to be moved.

473  
472  
557. A programmable infusion system in accordance with claim 556, wherein said plate comprises a permanent magnet.

474  
473  
✓ 558. A programmable infusion system in accordance with claim 553, further comprising means for limiting the distance said plate can move in both <sup>a</sup> the volume increasing direction and <sup>a</sup> the volume decreasing direction.

475  
466  
559. A programmable infusion system in accordance with claim 550, wherein said infusion means further comprises:

5  
P<sub>1</sub> an interface pressure <sup>valve</sup> ~~value~~ through which said selected medication enters said variable volume means from said medication reservoir, said interface pressure <sup>valve</sup> ~~value~~ being normally closed;

P<sub>1</sub> an outlet chamber which is in communication with said living body; and

P an outlet pressure valve located between said variable volume means and said outlet chamber, said outlet pressure valve being normally closed, an increase in volume of said variable volume means causing said interface pressure valve to open and medication to enter said variable volume means, a decrease in volume of said variable volume means causing said outlet pressure valve to open and said interface pressure valve to close, so as to permit medication to enter said outlet chamber as a pressure pulse.

E 475 <sup>476</sup> 560. A programmable infusion system in accordance with claim 559, wherein said outlet chamber comprises an elastic wall having a fluidic capacitive effect on the flow of said selected medication and a filter element through which liquid flow to the said <sup>living</sup> ~~lining~~ body is resisted, said elastic wall and said filter comprising a fluid resistance - capacitance arrangement with respect to said flow of said selected medication from said outlet chamber into said living body.

DI 464 <sup>465</sup> <sup>477</sup> 561. A programmable infusion system in accordance with claim 560, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.

477 <sup>478</sup> 562. A programmable infusion system in accordance with claim 561, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.

479 <sup>480</sup> 563. A programmable infusion system in accordance with claim 562, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said

living body, and means for receiving said telemetered  
operational information, ~~extended~~ <sup>external</sup> to said living body, wherein said  
infusion means further comprises an outlet chamber which is in  
communication with said living body, said pump means expelling  
said selected medication into said outlet ~~means~~ <sup>chamber</sup>, and means for  
monitoring the operation of said pump means, said monitoring  
means being disposed in said outlet chamber and providing a  
signal in response to a pressure pulse in said outlet chamber  
caused by said pump means, said monitoring means being operably  
coupled to said telemetry means.

479 <sup>480</sup> 564. A programmable infusion system in accordance with claim  
563, wherein said monitoring means comprises a pressure  
transducer.

D1 479 <sup>481</sup> 565. A programmable infusion system in accordance with claim  
563, further comprising first means for indicating the operation  
of said pump means when a decrease in volume of said variable  
volume means is not followed by a signal from said monitoring  
means corresponding to a pressure pulse of said selected  
medication expelled into said outlet chamber, said first  
indicating means being operably coupled to said telemetry means.

481 <sup>482</sup> 566. A programmable infusion system in accordance with claim  
565, further comprising second means for indicating the operation  
of said pump means when a signal is provided by said monitoring  
means absent a decrease in volume of said variable volume means  
~~caused by said moving means~~, said second indicating means being  
operably coupled to said telemetry means.

✓ 482 <sup>483</sup> 567. A programmable infusion system in accordance with claim  
566, further comprising means for telemetering operational  
information pertaining to said infusion apparatus out of said



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E

living body, ~~and~~ <sup>information</sup> means for receiving said telemetered operational ~~infusion~~ external to said living body, and means for monitoring the operation of said pump means, said monitoring means being operably coupled to said telemetry means.

<sup>484</sup>  
~~485~~ 568. A programmable infusion system in accordance with claim 567, wherein said monitoring means comprises pressure sensing means disposed in the path of flow of said selected medication into said living body, said pressure sensing means providing a signal in response to a pressure pulse in said path of flow.

CLAIMS E 36  
485-492  
ON  
YELLOW

569. A programmable infusion system in accordance with claim 568, further comprising first means for indicating the operation of said pump means when a decrease of volume of said variable volume means is ~~not~~ followed by a signal from said monitoring means corresponding to a pressure pulse of said selected medication expelled into said outlet chamber, said first indicating means being operably coupled to said telemetry means.

DI

N  
K  
E  
N

<sup>486</sup>  
~~485~~ 570. A programmable infusion system in accordance with claim 569 further comprising second means for indicating the operation of said pump means when a signal is provided by said monitoring means <sup>absent</sup> ~~about~~ a decrease in volume of said variable volume means ~~caused by said moving means~~, said second indicating means being operably coupled to said telemetry means.

~~485~~ E 37  
E 37

571. A programmable infusion system in accordance with claim 517, wherein one of said <sup>at least one</sup> remotely commandable operational characteristics comprises an infusion rate variable on command, said infusion apparatus further comprising means for inhibiting said infusion means from infusing said selected medication if a preselected medication infusion rate is exceeded, <sup>by a commanded infusion rate</sup> said inhibiting means being operably coupled to said infusion means.

81

<sup>488</sup>  
~~487~~ 572. A programmable infusion system in accordance with claim  
~~571~~, wherein said inhibiting means comprises at least one means  
for defining a fixed infusion rate limit.

E <sup>489</sup>  
~~488~~ 573. A programmable infusion system in accordance with claim  
~~572~~, wherein said <sup>at least one</sup> means for defining a fixed infusion rate limit  
is hardwired.

<sup>490</sup>  
~~487~~ 574. A programmable infusion system in accordance with claim  
~~571~~, wherein said preselected medication infusion rate is  
remotely selectable.

<sup>491</sup>  
~~487~~ 575. A programmable infusion system in accordance with claim  
~~571~~, wherein said preselected medication infusion rate comprises  
a remotely selectable rate and a fixed rate, said remotely  
selectable rate being limited by said fixed rate.

<sup>492</sup>  
~~487~~ 576. A programmable infusion system in accordance with claim  
~~571~~, wherein said inhibiting means comprises:

at least one programmable rate memory unit coupled to said  
command receiver means, each of said <sup>at least one</sup> programmable rate memory  
units for receiving and storing a infusion rate input command  
corresponding to said remotely selectable rate;

at least one limit control unit, each of <sup>said at least one limit control unit providing</sup> which provides a  
fixed rate limit; and

means for comparing each of said infusion rate input  
commands to a corresponding said fixed rate limit, infusion of  
said medication at a rate exceeding said fixed rate limit being  
inhibited.

E <sup>493</sup>  
~~492~~ 577. A programmable infusion system in accordance with claim  
~~576~~, further comprising command decoder means for coupling <sup>each of</sup> said  
at least one ~~said~~ programmable rate memory <sup>unit</sup> to said command

receiver means, said command decoder means for decoding said  
command signals received by said command receiver means into  
said infusion rate inputs for receipt by and storage in said at  
least one programmable rate memory <sup>units</sup> ~~unit~~. <sup>corresponding</sup>

494  
492 578. A programmable infusion system in accordance with claim  
576, wherein each of said <sup>at least one</sup> limit control units <sup>is</sup> ~~are~~ hardwired.

495  
492 579. A programmable infusion system in accordance with claim  
576, further comprising means for generating an alarm signal  
when any infusion rate input command exceeds a corresponding  
fixed rate limit.

496  
492 580. A programmable infusion system in accordance with claim  
578, wherein said inhibiting means precludes infusion of said  
medication by said infusion means when the selected said  
commandable infusion rate exceeds said preselected medication  
infusion rate during a ~~fixed~~ window <sup>of a predetermined length</sup> of time which shifts  
continuously.

497  
492 581. A programmable infusion system in accordance with claim  
577 wherein said inhibiting means precludes infusion of said  
medication by said infusion means when the selected said  
commandable infusion rate exceeds <sup>medication</sup> said preselected infusion rate  
during a ~~fixed~~ window <sup>of a predetermined length</sup> of time which shifts continuously.

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582. A programmable infusion system in accordance with claim  
571, wherein said infusion means includes a pump means which  
executes in pulses, said inhibiting means comprising a  
programmable memory <sup>rate unit</sup> coupled to said command receiver  
for storing initially a <sup>dose limit</sup> number corresponding to a first maximum  
number of infusion pulses preselected as allowable during a  
first shifting ~~maximum~~ time window of a predetermined length,

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pulse quantities being subtracted from said number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said stored number as time elapses such that said number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means ~~a~~ <sup>at a rate</sup> ~~number of times~~ in excess of said <sup>dose limit</sup> number stored in said programmable memory rate unit.

D1 583. A programmable infusion system in accordance with claim 582, wherein said memory rate unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted <sup>as a result of the lapse of time</sup> from said number stored in said programmable memory rate unit. <sup>dose limit</sup>

584. A programmable infusion system in accordance with claim 582, wherein said programmable memory rate unit also stores initially another <sup>dose limit</sup> number corresponding to a second maximum number of infusion pulses preselected as allowable during a second shifting time window of a predetermined length, said second shifting time window being longer in length than said first shifting time window, pulse quantities being subtracted from said <sup>dose limit</sup> another number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said <sup>dose limit</sup> another number as time elapses such that said <sup>dose limit</sup> another number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means <sup>at a rate</sup> ~~a number of times~~ in excess of <sup>the rate represented by dose limit</sup> said <sup>dose limit</sup> another number stored in said programmable memory ~~rate unit.~~

<sup>501</sup>  
~~585~~ 585. A programmable infusion system in accordance with claim  
<sup>560</sup>  
~~584~~, wherein said rate memory unit also records the number of  
pulses which have been inhibited and causes said pump means of  
said infusion means to execute said pulses when said pulses can  
be subtracted from <sup>both said dose limit</sup> ~~said~~ numbers stored in said programmable  
memory rate unit. <sup>^</sup>

<sup>502</sup>  
~~586~~ 586. A programmable infusion system in accordance with claim  
<sup>501</sup>  
~~585~~, wherein said inhibiting means further comprises at least  
one fixed infusion rate limit which limits the total maximum  
infusion rate of said infusion means.

<sup>503</sup>  
~~587~~ 587. A programmable infusion system in accordance with claim  
<sup>502</sup>  
~~586~~, wherein said fixed infusion rate limit is hardwired.

<sup>504</sup>  
~~588~~ 588. A programmable infusion system in accordance with claim  
<sup>501</sup>  
~~584~~, further comprising means for generating an alarm signal  
when any commanded infusion rate results in the inhibiting of  
pulsing of said pump means by said inhibiting means.

<sup>505</sup>  
~~589~~ 589. A programmable infusion system in accordance with claim  
<sup>504</sup>  
~~588~~, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

<sup>506</sup>  
~~590~~ 590. A programmable infusion system in accordance with claim  
<sup>560</sup>  
~~584~~, further comprising command decoder means for coupling said  
command receiver means to said programmable memory rate unit,  
said command decoder means for decoding said command signals  
received by said command receiver means into said first and  
second <sup>maximum</sup> numbers of infusion pulses. <sup>^</sup>

507  
467-591. A programmable infusion system in accordance with claim 591, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, said operational information including information pertaining to the functions of said inhibiting means, and means for receiving said telemetered operational information external to said living body.

508  
433-592. A programmable infusion system in accordance with claim 592, wherein said infusion means includes means for pumping a preselected amount of medication into said living body, said infusion apparatus further comprising means for recording the rate at which pumping is effected by said <sup>pump</sup> ~~pumping~~ means.

8  
C/A/AK Sub E 40  
594-511 593. A programmable infusion system in accordance with claim 592, wherein said recording means comprises:

DI  
means for storing the rate at which said ~~pumping~~ means pumps over a preselected time period;

means for storing a programmable input corresponding to a minimum medication infusion rate; and

means for comparing the rate recorded by said <sup>first recited</sup> ~~recording~~ means to the rate stored in said <sup>second recited</sup> ~~storing~~ means.

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594. A programmable infusion system in accordance with claim 593, further comprising means for providing an alarm signal when said rate recorded by said recording means is less than said <sup>input corresponding to said</sup> ~~programmable~~ minimum medication infusion rate.  
<sup>recorded by said second recited storing means.</sup>

511  
509-595. A programmable infusion system in accordance with claim 593, further comprising means for telemetering information <sup>recorded</sup> ~~deduced~~ by said recording means out of said living body, said telemetry means being coupled to said recording means and means for receiving said telemetered <sup>information</sup> ~~injection~~ external to said living body.

<sup>512</sup>  
~~506~~ 596. A programmable infusion system in accordance with claim  
~~592~~, wherein said recording means comprises:

ε P<sub>1</sub> means for storing the rate at which said <sup>pump</sup>~~pumping~~ means pumps  
over a preselected time period; and

ε P<sub>1</sub> means for storing the rate at which said <sup>pump</sup>~~pumping~~ means is  
signalled to pump over said preselected time period.

<sup>513</sup>  
~~512~~ 597. A programmable infusion system in accordance with claim  
~~596~~, further comprising means for comparing the rates recorded  
by both said storing means.

<sup>514</sup>  
~~513~~ 598. A programmable infusion system in accordance with claim  
~~597~~, further comprising means for telemetering information  
ε <sup>outputted</sup>~~deduced~~ by said comparing means out of said living body, said  
comparing means being coupled to said telemetry means, and means  
for receiving said telemetered information external to said  
living body.

D1  
<sup>515</sup>  
~~513~~ 599. A programmable infusion system in accordance with claim  
~~597~~, further comprising means for providing an alarm signal when  
ε the rate at which said <sup>pump</sup>~~pumping~~ means pumps is different than the  
ε rate at which said <sup>pump</sup>~~pumping~~ means <sup>is</sup>~~is~~ signalled to pump.

<sup>516</sup>  
~~512~~ 600. A programmable infusion system in accordance with claim  
~~596~~, further comprising means for telemetering information  
ε recorded by ~~both~~ said recording means out of said living body,  
ε ~~both~~ said recording means being coupled to said telemetry means,  
and means for receiving said telemetered information external to  
said living body.

<sup>517</sup>  
~~506~~ 601. A programmable infusion system in accordance with claim  
~~592~~, wherein said pump means executes in pulses, said recording  
means comprising a pulse rate detector comprising:

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E P means for counting the number of times said <sup>pump</sup>~~pumping~~ means pumps over a preselected time period, said counting means storing the count;

P minimum rate memory means for storing a programmable number input corresponding to a minimum medication infusion rate; and

P means for comparing the number counted by said counting means with said programmable number input stored in said minimum rate memory means.

<sup>518</sup>  
~~517~~ <sup>518</sup> 602. A programmable infusion system in accordance with claim ~~601~~, further comprising means for providing an alarm signal when said count is less than said programmable number input stored in said minimum rate memory means.

<sup>519</sup>  
~~518~~ <sup>519</sup> 603. A programmable infusion system in accordance with claim ~~602~~, wherein said alarm signal comprises a subcutaneous electrical stimulation.

D1 <sup>520</sup>  
~~518~~ <sup>520</sup> 604. A programmable infusion system in accordance with claim ~~602~~, wherein said counting means comprises a pressure transducer.

<sup>520</sup>  
~~518~~ <sup>520</sup> 605. A programmable infusion system in accordance with claim ~~602~~, further comprising means for telemetering information <sup>outputted</sup> ~~deduced~~ by said comparing means out of said living body, said comparing means being coupled to said telemetry means, and means for receiving said telemetered operational information external to said living body.

<sup>521</sup>  
~~518~~ <sup>521</sup> 606. A programmable infusion system in accordance with claim ~~502~~, wherein said pump means executes in pulses, said recording means comprising a pulse recorder comprising:

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E P means for counting the number of times said <sup>pump</sup>~~pumping~~ means pumps over a preselected time period, said counting means storing the count; and

E P means for counting the number of times said <sup>pump</sup>~~pumping~~ means is commanded to pump over said preselected time period.

523  
522  
607. A programmable infusion system in accordance with claim 606, wherein said pulse recorder further comprises means for comparing the ~~number~~<sup>number</sup> recorded by both said counting means.

524  
527  
607. A programmable infusion system in accordance with claim 607, further comprising means for telemetering information ~~outputted~~<sup>outputted</sup> by said comparing means out of said living body, said comparing means being coupled to said telemetry means, and means for receiving said telemetered information external to said living body.

525  
522  
609. A programmable infusion system in accordance with claim 608, further comprising means for providing an alarm signal when said numbers recorded by both said counting means are different.

526  
525  
610. A programmable infusion system in accordance with claim 609, wherein said alarm signal comprises a subcutaneous electrical stimulation.

527  
522  
611. A programmable infusion system in accordance with claim 610, further comprising means for telemetering information recorded by both said counting means out of said living body, said recording means being coupled to said telemetry means, and means for receiving said telemetered information external to said living body.

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528  
522 ~~612~~. A programmable infusion system in accordance with claim  
506, wherein said first recited counting means comprises a  
pressure transducer.

529  
438 ~~613~~. A programmable infusion system in accordance with claim  
517, further comprising means for maintaining the pressure  
within said medication reservoir at a pressure level below the  
internal pressure of said living body.

530  
529 ~~614~~. A programmable infusion system in accordance with claim  
613, wherein said pressure maintaining means comprises:

P<sub>1</sub> a flexible diaphragm which divides said medication reservoir  
into a medication chamber and a liquid-vapor pool chamber; and  
P<sub>1</sub> a liquid vapor pool disposed within said liquid-vapor pool  
chamber, the proportion of liquid to vapor in said liquid-vapor  
pool varying in response to variations in the amount of said  
selected medication disposed in said medication chamber.

D1

531  
530 ~~615~~. A programmable infusion system in accordance with claim  
614, further comprising means for telemetering operational  
information pertaining to said infusion apparatus out of said  
living body, and means for receiving said telemetered  
operational information external to said living body, said  
infusion apparatus further comprising switch means disposed  
within said medication reservoir, said switch means being  
coupled to said telemetry means and being activated when said  
flexible diaphragm is disposed in a preselected relationship  
relative to said switch means, said telemetry means telemetering  
a signal indicative of such an operational condition to said  
telemetering receiving means.

532  
E 531 ~~616~~. A programmable infusion system in accordance with claim  
615, wherein said switch means is activated by pressure exerted

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thereon by said flexible diaphragm, said pressure being less than the ambient pressure of said body.

533  
536-617. A programmable infusion system in accordance with claim  
-614, said infusion apparatus further comprising an antechamber through which access is gained to said medication reservoir, and a reservoir inlet valve located between said antechamber and said medication chamber, said reservoir inlet valve being operable ~~and~~ when the pressure in said antechamber exceeds the pressure in the ~~reservoir~~ <sup>said medication</sup> chamber by more than a predetermined differential.

534  
533-618. A programmable infusion system in accordance with claim  
-617, wherein the volume of said antechamber is less than 10% the volume of said ~~reservoir~~ <sup>medication</sup> chamber.

535  
534-619. A programmable infusion system in accordance with claim  
-617, further comprising an inlet filter means operably disposed between said antechamber and said medication chamber for preventing impurities in said selected medication in said antechamber from passing into said medication chamber when said reservoir inlet valve is opened, said filter means also preventing said selected medication in said medication chamber from rapidly entering said living body in the event of a leak in said inlet valve.

536  
534-620. A programmable infusion system in accordance with claim  
-617, further comprising means for programmed pumping of fixed-volume pulses of medication into said living body.

537  
534-621. A programmable infusion system in accordance with claim  
-617, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said

living body, means for receiving said telemetered operational information external to said living body, and means for injecting medication into said medication reservoir, said injecting means being coupled to said telemetry receiver means, and programming means coupled to said <sup>telemetry</sup> ~~telemetering~~ means for indicating when injection of medication into said medication reservoir is appropriate.

538  
622. A programmable infusion system for providing medication to a living body <sup>of a patient</sup> comprising:

P<sub>1</sub> an infusion apparatus for implantation in said living body, said apparatus including

P<sub>2</sub> a medication reservoir for storing selected medication,

P<sub>2</sub> means for infusing said selected medication stored in said medication reservoir into said living body, said infusion means having at least one remotely commandable operational characteristic and including means for pumping a preselected amount of medication into said living body,

P<sub>2</sub> means for recording the rate at which pumping is effected by said <sup>pump</sup> ~~pumping~~ means, and

P<sub>2</sub> command receiver means coupled to said infusion means for receiving command signals; and

P<sub>1</sub> command source means external to said living body for transmitting said command signals to be received by said command receiver means.

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539-540  
623. A programmable infusion system in accordance with claim 622, wherein said recording means comprises:

means for <sup>scoring</sup> ~~scoring~~ the rate at which said <sup>pumping</sup> ~~pumping~~ means pumps over a preselected time period;

N  
L  
N  
P means for storing a programmable input corresponding to a minimum medication infusion rate; and

means for comparing the rate recorded by said <sup>first recited storing</sup> recording means to the rate stored in said <sup>second recited</sup> storing means.

624. A programmable infusion system in accordance with claim 623, further comprising means for providing an alarm signal when said rate recorded by said <sup>first recited storing</sup> recording means is less than said programmable <sup>input corresponding to said</sup> minimum medication infusion rate. <sup>recorded by said second recited storing means.</sup>

541  
539  
E 625. A programmable infusion system in accordance with claim 623, further comprising means for telemetering information <sup>recorded</sup> deduced by said recording means out of said living body, said telemetry means being coupled to said recording means, and means for receiving said telemetered information external to said living body.

D1  
542  
538  
E 626. A programmable infusion system in accordance with claim 622, wherein said recording means comprises:

E P<sub>1</sub> means for storing the rate at which said <sup>pump</sup> ~~pumping~~ means pumps over a preselected time period; and

E P<sub>1</sub> means for storing the rate at which said <sup>pump</sup> ~~pumping~~ means is signalled to pump over said preselected time period.

543  
542  
E 627. A programmable infusion system in accordance with claim 626, further comprising means for comparing the rates recorded by both said storing means.

544  
543  
E 628. A programmable infusion system in accordance with claim 627, further comprising means for telemetering information <sup>outputted</sup> deduced by said comparing means out of said living body, said comparing means being coupled to said telemetry means, and means for receiving said telemetered information external to said living body.

545  
629. A programmable infusion system in accordance with claim  
543  
627, further comprising means for providing an alarm signal when  
the rate at which said <sup>pump</sup>~~pumping~~ means pumps is different than the  
rate at which said <sup>pump</sup>~~pumping~~ means <sup>is</sup>~~is~~ signalled to pump.

546  
630. A programmable infusion system in accordance with claim  
542  
628, further comprising means for telemetering information  
recorded by ~~both~~ said recording means out of said living body,  
~~both~~ said recording means being coupled to said telemetry means,  
and means for receiving said telemetered information external to  
said living body.

547  
631. A programmable infusion system in accordance with claim  
538  
622, wherein said pump means executes in pulses, said recording  
means comprising a pulse rate detector comprising:

D<sup>2</sup> 1 P<sub>1</sub> means for counting the number of times said <sup>pump</sup>~~pumping~~ means  
pumps over a preselected time period, said counting means  
storing the count;

P<sub>1</sub> minimum rate memory means for storing a programmable number  
input corresponding to a minimum medication infusion rate; and

P<sub>1</sub> means for comparing the number counted by said counting  
means with said programmable number input stored in said minimum  
rate memory means.

548  
632. A programmable infusion system in accordance with claim  
547  
631, further comprising means for providing an alarm signal when  
said count is less than said programmable number input stored in  
said minimum rate memory means.

549  
633. A programmable infusion system in accordance with claim  
548  
632, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

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<sup>550</sup>  
~~548~~ 634. A programmable infusion system in accordance with claim  
~~632~~, wherein said counting means comprises a pressure  
transducer.

<sup>551</sup>  
~~548~~ 635. A programmable infusion system in accordance with claim  
~~632~~, further comprising means for telemetering information  
<sup>outputted</sup>  
~~deduced~~ by said comparing means out of said living body, said  
comparing means being coupled to said telemetry means, and means  
for receiving said telemetered operational information external  
to said living body.

✓ <sup>552</sup>  
~~538~~ 636. A programmable infusion system in accordance with claim  
~~622~~, wherein said pump means executes in pulses, said recording  
means comprising a pulse recorder comprising:

D/E P<sub>1</sub> means for counting the number of times said <sup>pump</sup>~~pumping~~ means  
pumps over a preselected time period, said counting means  
storing the count; and

E P<sub>1</sub> means for counting the number of times said <sup>pump</sup>~~pumping~~ means is  
commanded to pump over said preselected time period.

↓ <sup>553</sup>  
~~552~~ 637. A programmable infusion system in accordance with claim  
~~636~~, wherein said pulse recorder further comprises means for  
E comparing the <sup>numbers</sup>~~number~~ recorded by both said counting means.

<sup>554</sup>  
~~553~~ 638. A programmable infusion system in accordance with claim  
~~637~~, further comprising means for telemetering information  
E <sup>outputted</sup>  
~~deduced~~ by said comparing means out of said living body, said  
comparing means being coupled to said telemetry means, and means  
for receiving said telemetered information external to said  
living body.

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✓ 552 <sup>555</sup>  
~~554~~ 639. A programmable infusion system in accordance with claim  
~~636~~, further comprising means for providing an alarm signal when  
said numbers recorded by both said counting means are different.

<sup>556</sup>  
~~555~~ 640. A programmable infusion system in accordance with claim  
~~639~~, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

✓ <sup>557</sup>  
~~554~~ 641. A programmable infusion system in accordance with claim  
~~636~~, further comprising means for telemetering information  
recorded by both said counting means out of said living body,  
said recording means being coupled to said telemetry means, and  
means for receiving said telemetered information external to  
said living body.

✓ <sup>558</sup>  
~~554~~ 642. A programmable infusion system in accordance with claim  
~~636~~, wherein said first recited counting means comprises a  
pressure transducer.

D1

<sup>559</sup>  
~~538~~ 643. A programmable infusion system in accordance with claim  
~~622~~, wherein one of said command signals transmitted by said  
command source means comprises a signal which corresponds to a  
selected operational rate at which said infusion means will  
infuse said selected medication into said living body.

<sup>560</sup>  
~~538~~ 644. A programmable infusion system in accordance with claim  
~~622~~, further comprising means for telemetering operational  
information pertaining to said infusion apparatus out of said  
living body, and means for receiving said telemetered  
operational information external to said living body, wherein  
said command source and said telemetry receiving means are  
embodied in a patient programming unit external to said living  
body, said patient programming unit having a plurality of



operational medication dose inputs each corresponding to a medication infusion rate selectable and requestable by the patient, said patient programming unit for selectively transmitting a command signal corresponding to a selected <sup>one of</sup> said medication dose <sup>input</sup> ~~input~~.

561  
560  
645. A programmable infusion system in accordance with Claim 644, wherein said infusion apparatus further comprises electronic control means coupled to said infusion means and said command receiver means, said <sup>electronic</sup> ~~electric~~ control means <sup>including means</sup> for maintaining a history of the infusion rate at which said infusion means has operated, said <sup>including means</sup> ~~electric~~ control means for precluding the infusion of said selected medication by said infusion means if said rate requested by said patient programming unit exceeds a predetermined safe medication infusion rate based on said maintained history.

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561  
646. A programmable infusion system in accordance with claim 645, wherein said electronic control means is coupled to said telemetry means, said patient programming unit including means for indicating to said patient if said selected infusion rate exceeds said predetermined safe medication infusion rate, said <sup>electric</sup> ~~selective~~ control means selectively sending a signal to said indicating means via said telemetry means and said telemetry receiving means, said telemetry receiving means being coupled to said indicating means.

563  
561  
647. A programmable infusion system in accordance with claim 645, wherein said patient programming unit further comprises annunciator means and visual display means for providing information regarding previously selected medication infusion rates, for indicating whether a proper programming of a presently requested infusion rate has been communicated to said

command receiver, and for selectively providing information as to the time and rate of previously selected medication infusion.

<sup>564</sup>  
~~648~~ 538. A programmable infusion system in accordance with claim ~~622~~, further comprising means for selectively supplying power to said command receiver means, said supply means being coupled to an external power source, said supply means being external to said living body, said infusion means being powered by an implanted power source.

<sup>565</sup>  
~~649~~ 564. A programmable infusion system, in accordance with claim ~~648~~, wherein said supply means provides an alternating field.

<sup>566</sup>  
~~650~~ 565. A programmable infusion system, in accordance with claim ~~649~~, wherein said infusion apparatus further comprises detector means for detecting said alternating field and for converting the same into electrical energy, said detecting means being coupled to said command receiver.

<sup>567</sup>  
~~651~~ 566. A programmable infusion system in accordance with claim ~~650~~, wherein said infusion apparatus further comprises means for rectifying said electrical energy into a d.c. power signal.

<sup>568</sup>  
~~652~~ 567. A programmable infusion system in accordance with claim ~~651~~, wherein said d.c. power signal is coupled to said implanted power source to effect the charging thereof.

<sup>569</sup>  
~~653~~ 568. A programmable infusion system in accordance with claim ~~652~~, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, said

telemetry means being coupled to said rectifier means and being powered by said d.c. power signal.

<sup>570</sup>~~654~~. A programmable infusion system in accordance with claim <sup>564</sup>~~648~~, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, said telemetry means also being supplied power by said supply means.

<sup>571</sup>~~655~~. A programmable infusion system in accordance with claim <sup>564</sup>~~648~~, further comprising means for selectively recharging said implanted power source, said recharging means being powered by said supply means.

<sup>572</sup>~~656~~. A programmable infusion system in accordance with claim <sup>538</sup>~~622~~, wherein said infusion means comprises a fluid handling mechanism, said fluid handling mechanism including said pump means, said operational information including information about the operation of said fluid handling mechanism.

<sup>573</sup>~~657~~. A programmable infusion system in accordance with claim <sup>575</sup>~~656~~, wherein the amount of medication pumped by said pump means is controlled by a pressure limit in the said pump means.

<sup>574</sup>~~658~~. A programmable infusion system in accordance with claim <sup>573</sup>~~656~~, wherein said pump means operates in a pulsatile mode. ✓

<sup>575</sup>~~659~~. A programmable infusion system in accordance with claim <sup>574</sup>~~658~~, wherein said pump means pumps a fixed volume of said selected medication each time said pump means is pulsed.

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660. A programmable infusion system in accordance with claim 656, wherein said pump <sup>mean</sup> comprises variable volume means for storing said selected medication within said <sup>at least one,</sup> pump means, an increase in volume of said variable volume means permitting drawing of said selected medication into said pump means, a decrease in volume of said variable volume means permitting expulsion of said selected medication from said pump means.

577  
576  
661. A programmable infusion system in accordance with claim 660, wherein said variable volume means comprises at least one flexible wall, movement of said flexible wall varying the volume of said variable volume means <sup>at least one</sup>, and means for moving said <sup>at least one</sup> flexible wall.

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0  
6  
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P  
662. A programmable infusion system in accordance with claim 661, further comprising spring means for urging said <sup>at least one flexible</sup> wall in a manner which decreases the volume of said variable volume means, the magnitude of the force applied to and stored by said spring means increasing as the volume of said variable volume means increases due to the displacement of said <sup>at least one</sup> flexible wall thereof by said moving means.

663. A programmable infusion system in accordance with claim 662, wherein said <sup>at least one</sup> flexible wall comprises a bellows assembly having mounted on one end thereof a plate, the other end of said bellows <sup>assembly</sup> being in communication with said selected medication, the walls of said bellows <sup>assembly</sup> serving as said spring means.

580  
579  
664. A programmable infusion system in accordance with claim 663, wherein said plate has a surface in contact with said selected medication when drawn into said variable volume means.

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581  
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665. A programmable infusion system in accordance with claim  
664, wherein said bellows <sup>assembly</sup> is inhibited from moving said plate  
when the pressure (p) in said variable volume means exceeds the  
spring force (F) of said bellows <sup>assembly</sup> divided by the wetted area (A)  
of said surface of said plate in contact with said selected  
medication, that is when  $p > \frac{F}{A}$ .

Sub E44  
666. A programmable infusion system in accordance with claim  
563, wherein said moving means comprises said plate being <sup>is</sup>  
magnetizable, <sup>and moving means comprising</sup> and a coil disposed proximate to said plate, said  
coil selectively radiating a pulsing magnetic field, pulsing of  
said coil causing said plate to be moved.

583  
582  
667. A programmable infusion system in accordance with claim  
666, wherein said plate comprises a permanent magnet.

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D1 583  
668. A programmable infusion system in accordance with claim  
583, further comprising means for limiting the distance said  
plate can move in both <sup>a</sup> the volume increasing direction and <sup>a</sup> the  
volume decreasing direction.

585  
586  
669. A programmable infusion system in accordance with claim  
668, wherein said infusion means further comprises:  
P<sub>1</sub> an interface pressure <sup>valve</sup> ~~value~~ through which said selected  
medication enters said variable volume means from said  
medication reservoir, said interface pressure valve being  
normally closed;  
P<sub>1</sub> an outlet chamber which is in communication with said living  
body; and  
P<sub>1</sub> an outlet pressure valve located between said variable  
volume means and said outlet chamber, said outlet pressure valve  
being normally closed, an increase in volume of said variable  
volume means causing said interface pressure valve to open and

medication to enter said variable volume means, a decrease in volume of said variable volume means causing said outlet pressure valve to open and said interface pressure valve to close, so as to permit medication to enter said outlet chamber as a pressure pulse.

<sup>586</sup>  
~~585~~ 669. A programmable infusion system in accordance with claim 669, wherein said outlet chamber comprises an elastic wall having a fluidic capacitive effect on the flow of said selected medication and a filter element through which liquid flow to the said <sup>living</sup> ~~lining~~ body is resisted, said elastic wall and said filter comprising a fluid resistance - capacitance arrangement with respect to said flow of said selected medication from said outlet chamber into said living body.

<sup>587</sup>  
~~586~~ 671. A programmable infusion system in accordance with claim 671, further comprising means for feeding said selected medication into said living body from said pump means in a flow which decays exponentially over time.

<sup>588</sup>  
~~587~~ 672. A programmable infusion system in accordance with claim 672, wherein said feeding means comprises a mechanical resistance (R) and a mechanical capacitance (C) circuit resulting in an exponentially decaying outflow of medication for each said fixed volume pulse.

<sup>589</sup>  
~~588~~ 673. A programmable infusion system in accordance with claim 673, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information <sup>external</sup> ~~extended~~ to said living body, wherein said infusion means further comprises an outlet chamber which is in communication with said living body, said pump means

8 expelling said selected medication into said outlet <sup>chambers, ✓</sup> means; and 8  
means for monitoring the operation of said pump means, said  
monitoring means being disposed in said outlet chamber and  
E <sup>providing</sup> providing a signal in response to a pressure pulse in said outlet  
chamber caused by said pump means, said monitoring means being  
operably coupled to said telemetry means.

<sup>590</sup>  
~~589-674~~. A programmable infusion system in accordance with claim  
~~673~~, wherein said monitoring means comprises a pressure  
transducer.

<sup>591</sup>  
~~589~~ <sup>675</sup>. A programmable infusion system in accordance with claim  
~~673~~, further comprising first means for indicating the operation  
of said pump means when a decrease in volume of said variable  
volume means is not followed by a signal from said monitoring  
means corresponding to a pressure pulse of said selected  
medication expelled into said outlet chamber, said first  
indicating means being operably coupled to said telemetry means.

D1  
<sup>592</sup>  
~~591~~ <sup>676</sup>. A programmable infusion system in accordance with claim  
~~675~~, further comprising second means for indicating the operation  
of said pump means when a signal is provided by said monitoring  
means absent a decrease in volume of said variable volume means  
E ~~caused by said monitoring means~~, said second indicating means being  
operably coupled to said telemetry means.

<sup>593</sup> ✓  
~~582~~ <sup>677</sup>. A programmable infusion system in accordance with claim  
~~676~~, further comprising means for telemetering operational  
572 information pertaining to said infusion apparatus out of said  
E living body, ~~and~~ means for receiving said telemetered  
E operational <sup>information</sup> ~~infusion~~ external to said living body, and means for  
monitoring the operation of said pump means, said monitoring  
means being operably coupled to said telemetry means.

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594  
678. A programmable infusion system in accordance with claim  
593  
677, wherein said monitoring means comprises pressure sensing  
means disposed in the path of flow of said selected medication  
into said living body, said pressure sensing means providing a  
signal in response to a pressure pulse in said path of flow.

CLAIM 8 45  
595-596  
679. A programmable infusion system in accordance with claim  
678, further comprising first means for indicating the operation  
of said pump means when a decrease in volume of said variable  
volume means is not followed by a signal from said monitoring  
means corresponding to a pressure pulse of said selected  
medication expelled into said outlet chamber, said first  
indicating means being operably coupled to said telemetry means.

594  
595  
679. A programmable infusion system in accordance with claim  
678, further comprising second means for indicating the  
operation of said pump means when a signal is provided by said  
monitoring means absent a decrease in volume of said variable  
volume means ~~caused by said moving means~~, said second indicating  
means being operably coupled to said telemetry means.

591  
594  
681. A programmable infusion system in accordance with claim  
680, wherein one of said <sup>at least one</sup> remotely commandable operational  
~~characteristic~~ <sup>characteristic</sup> comprises an infusion rate variable on command,  
said infusion apparatus further comprising means for inhibiting  
said infusion means from infusing said selected medication if a  
preselected medication infusion rate is exceeded, said  
inhibiting means being operably coupled to said infusion means.

598  
597  
682. A programmable infusion system in accordance with claim  
681, wherein said inhibiting means comprises at least one means  
for defining a fixed infusion rate limit.



599  
683. A programmable infusion system in accordance with claim  
598, wherein said <sup>at least one</sup> means for defining a fixed infusion rate limit  
is hardwired.

600  
597  
684. A programmable infusion system in accordance with claim  
681, wherein said preselected medication infusion rate is  
remotely selectable.

601  
597  
685. A programmable infusion system in accordance with claim  
681, wherein said preselected medication infusion rate comprises  
a remotely selectable rate and a fixed rate, said remotely  
selectable rate being limited by said fixed rate.

Sub 846  
686. A programmable infusion system in accordance with claim  
682, wherein said inhibiting means comprises:  
at least one programmable rate memory unit coupled to said  
command receiver means, each of said <sup>at least one</sup> programmable rate memory  
units for receiving and storing <sup>data</sup> an infusion rate input command  
corresponding to said remotely selectable rate;  
at least one limit control unit, each of <sup>said at least one limit control</sup> which provides a <sup>unit providing</sup>  
fixed rate limit; and  
means for comparing each of said infusion rate input  
commands to a corresponding said fixed rate limit, infusion of  
said medication at a rate exceeding said fixed rate limit being  
~~inhibited.~~

603  
687. A programmable infusion system in accordance with claim  
686, further comprising command decoder means for <sup>each of</sup> coupling said  
at least one ~~said~~ programmable rate memory <sup>units</sup> ~~unit~~ to said command  
receiver means, said command decoder means for decoding said  
command signals received by said command receiver means into  
said infusion rate inputs for receipt by and storage in <sup>corresponding</sup> said at  
least one programmable rate memory unit.

225

604  
602  
E 688. A programmable infusion system in accordance with claim 686, wherein each of said <sup>at least on</sup> limit control units <sup>is</sup> ~~are~~ hardwired.

605  
602  
689. A programmable infusion system in accordance with claim 686, further comprising means for generating an alarm signal when any infusion rate input command exceeds a corresponding fixed rate limit.

✓ 606  
605  
E 690. A programmable infusion system in accordance with claim 689, wherein said inhibiting means precludes infusion of said medication by said infusion means when the selected said commandable infusion rate exceeds said preselected medication infusion rate during a ~~fixed~~ <sup>of a predetermined</sup> window of time which shifts continuously.

DI 607  
E 691. A programmable infusion system in accordance with claim 597, wherein said inhibiting means precludes infusion of said medication by said infusion means when the selected said commandable infusion rate exceeds said <sup>medication</sup> preselected infusion rate during a ~~fixed~~ <sup>of a predetermined length</sup> window of time which shifts continuously.

CLAIMS E47  
EX-610  
ON  
EL  
UN  
N  
K  
N  
P  
692. A programmable infusion system in accordance with claim 681, wherein said pump means executes in pulses, said inhibiting means comprising a programmable memory rate unit coupled to said command receiver for storing initially a <sup>discrete</sup> number corresponding to a first maximum number of infusion pulses preselected as allowable during a first shifting time window of a predetermined length, pulse quantities being subtracted from said number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means, pulse quantities being added to said stored number as time elapses such that said number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral

fashion, said inhibiting means not permitting pulsing of said pump means <sup>at a rate</sup> ~~a number of times~~ <sup>the rate represented by</sup> in excess of said number stored in said programmable memory rate unit. <sup>dose limit</sup>

693. A programmable infusion system in accordance with claim 692, wherein said memory rate unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted from said <sup>dose limit</sup> number stored in said programmable memory rate unit as a result of the elapse of time.

N  
K  
R  
P  
694. A programmable infusion system in accordance with claim 692, wherein said programmable memory rate unit also stores initially another <sup>dose limit</sup> number corresponding to a second maximum number of infusion pulses preselected as allowable during a second shifting time window of a predetermined length, said second shifting time window being longer in length than said first shifting time window, pulse quantities being subtracted from said another <sup>dose limit</sup> number stored in said programmable memory rate unit as infusion pulses are executed by said infusion means; pulse quantities being added to said <sup>dose limit</sup> another stored number as time elapses such that said another <sup>dose limit</sup> number does not exceed said first maximum number, said subtraction and addition being accomplished in running integral fashion, said inhibiting means not permitting pulsing of said pump means <sup>at a rate</sup> ~~a number of times~~ in excess of said another <sup>dose limit</sup> number stored in said programmable memory ~~rate unit.~~

611  
610  
695. A programmable infusion system in accordance with claim 694, wherein said rate memory unit also records the number of pulses which have been inhibited and causes said pump means of said infusion means to execute said pulses when said pulses can be subtracted from said <sup>dose limit</sup> numbers stored in said programmable memory rate unit.  
E

<sup>612</sup>  
~~611~~ 696. A programmable infusion system in accordance with claim  
~~695~~, wherein said inhibiting means further comprises at least  
one fixed infusion rate limit which limits the total maximum  
infusion rate of said infusion means.

<sup>613</sup>  
~~612~~ 697. A programmable infusion system in accordance with claim  
~~696~~, wherein said fixed infusion rate limit is hardwired.

<sup>614</sup> ✓  
~~613~~ 698. A programmable infusion system in accordance with claim  
~~697~~, further comprising means for generating an alarm signal  
when any commanded infusion rate results in the inhibiting of  
pulsing of said pump means by said inhibiting means.

<sup>615</sup>  
~~614~~ 699. A programmable infusion system in accordance with claim  
~~698~~, wherein said alarm signal comprises a subcutaneous  
electrical stimulation.

D1  
<sup>616</sup>  
~~610~~ 700. A programmable infusion system in accordance with claim  
~~699~~, further comprising command decoder means for coupling said  
command receiver means to said programmable memory rate unit,  
said command decoder means for decoding said command signals  
received by said command receiver means into said first and  
second <sup>maximum</sup> numbers of infusion pulses.  
E

<sup>617</sup>  
~~538~~ 701. A programmable infusion system in accordance with claim  
~~622~~, further comprising means for telemetering operational  
information pertaining to said infusion apparatus out of said  
living body, said operational information including information  
pertaining to the functions of said inhibiting means, and means  
for receiving said telemetered operational information external  
to said living body.

618  
532  
622, 702. A programmable infusion system in accordance with claim  
said infusion apparatus further comprising means for  
generating a distinctive alarm signal pattern for each of a  
E plurality of improper <sup>operationally</sup> ~~operation~~ conditions.

CSAPME 48  
619-1531  
ON  
FOLLOW  
703. A programmable infusion system in accordance with claim  
702, wherein said alarm signal <sup>is delivered</sup> ~~is delivered~~ to said living body  
subcutaneously. <sup>pattern</sup>

704. A programmable infusion system in accordance with claim  
703, further comprising means for detecting a medication leak,  
said medication detecting means being  
coupled to said alarm means, wherein one of said improper  
operation <sup>at</sup> conditions comprises a medication leak out of said  
medication reservoir.

DK  
705. A programmable infusion system in accordance with claim  
703, further comprising means for detecting a body fluid leak,  
said body fluid detecting means being  
coupled to said alarm means, wherein one of said improper  
operation <sup>at</sup> conditions <sup>generating</sup> comprises a leak of body fluids into said  
infusion apparatus.

706. A programmable infusion system in accordance with claim  
703, further comprising means for detecting the rate at which  
said infusion means is operating, <sup>said rate detecting means being</sup> coupled to said alarm means,  
wherein one of said improper operation <sup>generating</sup> conditions comprises  
operation of said infusion means at an improper rate.

707. A programmable infusion system in accordance with claim  
703, wherein one of said improper operation <sup>at</sup> conditions comprises  
receiving of a command by said command receiver <sup>means</sup> which cannot be  
executed.

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708. A programmable infusion system in accordance with claim 703, further comprising <sup>a</sup> battery means for powering said infusion means and means for determining the voltage of said battery ~~means~~, <sup>voltage determination means being</sup> coupled to said alarm <sup>means</sup>, wherein one of said improper operation <sup>al</sup> conditions <sup>generating</sup> comprises low battery <sup>means</sup> voltage.

709. A programmable infusion system in accordance with claim 703, further comprising means for detecting the amount of <sup>said medication amount detecting means being</sup> medication disposed in said reservoir, coupled to said alarm <sup>means</sup> wherein one of said improper operation <sup>al</sup> conditions <sup>generating</sup> comprises a preselected amount of medication remaining in said medication reservoir.

710. A programmable infusion system in accordance with claim 702, further comprising means for detecting a medication leak, <sup>said medication detecting means being</sup> coupled to said alarm <sup>means</sup>, wherein one of said improper operation <sup>al</sup> conditions <sup>generating</sup> comprises a medication leak out of said ~~medication reservoir~~.

711. A programmable infusion system in accordance with claim 702, further comprising means for detecting a body fluid leak, <sup>said body fluid detecting means being</sup> coupled to said alarm means wherein one of said improper operation conditions comprises a leak of body fluids into said infusion apparatus.

712. A programmable <sup>S</sup> infusion system in accordance with claim 702, further comprising means for detecting the rate at which <sup>said rate detecting means being</sup> said infusion means is operating, coupled to said alarm <sup>means</sup>, wherein one of said improper operation <sup>al</sup> conditions <sup>generating</sup> comprises operation of said infusion means at an improper rate.

713. A programmable infusion system in accordance with claim 702, wherein one of said improper operation <sup>al</sup> conditions comprises

receiving of a command by said command receiver<sup>means</sup> which cannot be executed.

714. A programmable infusion system in accordance with claim 702, further comprising<sup>a</sup> battery means for powering said infusion means and means for determining the voltage of said battery<sup>means</sup>,<sup>said voltage determining means being</sup> coupled to said alarm means, wherein one of said improper operation<sup>al</sup> conditions<sup>is detecting</sup> comprises low battery<sup>means</sup> voltage.

715. A programmable infusion system in accordance with claim 702, further comprising means for detecting the amount of medication disposed in said reservoir<sup>said medication amount detecting means being</sup> coupled to said alarm<sup>means</sup> wherein one of said improper operation<sup>al</sup> conditions<sup>is generating</sup> comprises a preselected amount of medication remaining in said ~~medication reservoir.~~

632  
618  
716. A programmable infusion system in accordance with claim 702, further comprising means for simulating said improper operational conditions for test purposes.

633  
538  
717. A programmable infusion system in accordance with claim 702, further comprising means for maintaining the pressure within said medication reservoir at a pressure level below the internal pressure of said living body.

634  
633  
718. A programmable infusion system in accordance with claim 717, wherein said pressure maintaining means comprises:  
P<sub>1</sub> a flexible diaphragm which divides said medication reservoir into a medication chamber and a liquid-vapor pool chamber; and  
P<sub>1</sub> a liquid vapor pool disposed within said liquid-vapor pool chamber, the proportion of liquid to vapor in said liquid-vapor pool varying in response to variations in the amount of said selected medication disposed in said medication chamber.

<sup>635</sup>  
~~719~~ 719. A programmable infusion system in accordance with claim  
<sup>634</sup>  
~~718~~ further comprising means for telemetering operational  
information pertaining to said infusion apparatus out of said  
living body, and means for receiving said telemetered  
operational information external to said living body, said  
infusion apparatus further comprising switch means disposed  
within said medication reservoir, said switch means being  
coupled to said telemetry means and being activated when said  
flexible diaphragm is disposed in a preselected relationship  
relative to said switch means, said telemetry means telemetering  
a signal indicative of such an operational condition to said  
telemetry receiving means.

<sup>636</sup>  
<sup>635</sup>  
~~719~~ 720. A programmable infusion system in accordance with claim  
D1 wherein said switch means is activated by pressure exerted  
thereon by said flexible diaphragm, said pressure being less  
than the ambient pressure of said body.

<sup>637</sup>  
<sup>634</sup>  
~~718~~ 721. A programmable infusion system in accordance with claim  
E  
E said infusion apparatus further comprising an antechamber  
through which access is gained to said medication reservoir, and  
a reservoir inlet valve located between said antechamber and  
said medication chamber, said reservoir inlet valve being  
operable ~~and~~ when the pressure in said antechamber exceeds the  
pressure in <sup>said medication</sup> ~~the reservoir~~ chamber by more than a predetermined  
differential.

<sup>638</sup>  
<sup>637</sup>  
~~721~~ 722. A programmable infusion system in accordance with claim  
E wherein the volume of said antechamber is less than 10% the  
volume of said <sup>medication</sup> ~~reservoir~~ chamber. B

<sup>639</sup>  
<sup>638</sup>  
~~721~~ 723. A programmable infusion system in accordance with claim  
further comprising an inlet filter means operably disposed



between said antechamber and said medication chamber for preventing impurities in said selected medication in said antechamber from passing into said medication chamber when said inlet valve is opened, said filter means also preventing said ~~reservoir~~ <sup>reservoir</sup> selected medication in said medication chamber from rapidly entering said living body in the event of a leak in said inlet valve.

<sup>640</sup>  
~~535~~ <sup>724</sup>. A programmable infusion system in accordance with claim ~~622~~, further comprising means for programmed pumping of fixed-volume pulses of medication into said living body.

<sup>641</sup>  
~~535~~ <sup>725</sup>. A programmable infusion system in accordance with claim ~~622~~, further comprising means for telemetering operational information pertaining to said infusion apparatus out of said living body, and means for receiving said telemetered operational information external to said living body, and means for injecting medication into said medication reservoir, said injecting means being coupled to said ~~telemetering~~ <sup>telemetry</sup> receiver means, and programming means coupled to said ~~telemetering~~ <sup>telemetry</sup> means for indicating when injection of medication into said medication reservoir is appropriate.

<sup>642</sup>  
~~535~~ <sup>726</sup>. A programmable infusion system in accordance with claim ~~305~~, further comprising means for injecting medication into said medication reservoir, said injecting means being coupled to said ~~telemetering~~ <sup>telemetry</sup> receiver means, and programming means coupled to said ~~telemetering~~ <sup>telemetry</sup> means for indicating when ejection of medication into said medication reservoir is appropriate.

END

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